FOURTH IN A SERIES ON HEALTH CARE INFORMATION TECHNOLOGY

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES

ONE HUNDRED NINTH CONGRESS

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THURSDAY, APRIL 6, 2006

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The Subcommittee met, pursuant to notice, at 2:16 p.m., in room 1100, Longworth House Office Building, Hon. Nancy Johnson (Chairman of the Subcommittee) presiding.ab
[The advisory announcing the hearing follows:]

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE   CONTACT: (202) 225–3943
March 30, 2006
No. HL–14

Johnson Announces Fourth in Series on Health Care Information Technology

Congresswoman Nancy L. Johnson (R–CT), Chairman, Subcommittee on Health of the Committee on Ways and Means, today announced that the Subcommittee will hold a hearing on health information technology (IT). **The hearing will take place on Thursday, April 6, 2006, in the main Committee hearing room, 1100 Longworth House Office Building, beginning at 2:00 p.m.**

In view of the limited time available to hear witnesses, oral testimony at this hearing will be from invited witnesses only. Witnesses will include representatives from the public and private sectors to discuss processes currently in place to develop and adopt IT standards, how systems are currently being used in the private sector, and what additional actions are required to expand adoption over the next few years. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

BACKGROUND:

Greater use of IT in the health care field has the potential to reduce medical errors, improve patient care, and reduce costs; yet adoption of new technology has been slow. President Bush has stated a goal of providing most Americans with electronic health records by 2014. To further this goal, Secretary of Health and Human Services Michael Leavitt is chairing the American Health Information Community (AHIC), comprised of 17 members from the public and private sectors, to develop IT standards and achieve health IT interoperability. The AHIC will be developing recommendations by the end of 2006 in four areas: consumer empowerment, chronic care, biosurveillance, and electronic health records.

While this public-private partnership represents an important step in furthering adoption of health IT, additional actions are needed by both the public and private sectors to achieve the President's goal. Congress can learn from the experience of public and private entities that are implementing health IT systems as to what additional actions are required to realize the ultimate goal of a secure, nationwide health care information infrastructure that ensures that necessary information is available to health care providers when they need it in order to provide the best patient care.

This hearing is the fourth in a series that the Subcommittee is holding on health IT, covering private sector initiatives, government programs, and electronic prescribing. This hearing will focus on recent developments in this area, legislation that has been introduced to address these issues, and ways in which Congress can act to ensure continued progress.

In announcing the hearing, Chairman Johnson stated, "I have long been a champion of increasing the use of health IT, and I applaud the steps being taken by Secretary Leavitt to foster a public-private dialogue to accelerate progress in this area. Congress must learn from the successful health IT programs already in place in the private sector to determine how we can best assist in expanding the use of health IT to all providers, thus providing benefits of this technology to people across the country."

FOCUS OF THE HEARING:

The hearing will focus on the progress currently being made through public and private efforts to increase adoption of health IT, and areas where specific legislative changes may be required to further these efforts.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Please Note: Any person(s) and/or organization(s) wishing to submit for the hearing record must follow the appropriate link on the hearing page of the Committee website and complete the informational forms. From the Committee homepage, *http://waysandmeans.house.gov*, select "*109th Congress*" from the menu entitled, "*Hearing Archives*" (*http://waysandmeans.house.gov/Hearings.asp?congress=17*). Select the hearing for which you would like to submit, and click on the link entitled, "*Click here to provide a submission for the record.*" Once you have followed the online instructions, completing all informational forms and clicking "submit" on the final page, an email will be sent to the address which you supply confirming your interest in providing a submission for the record. You ***MUST REPLY*** to the email and ***ATTACH*** your submission as a Word or WordPerfect document, in compliance with the formatting requirements listed below, by close of business Thursday, April 20, 2006. **Finally**, please note that due to the change in House mail policy, the U.S. Capitol Police will refuse sealed-package deliveries to all House Office Buildings. For questions, or if you encounter technical problems, please call (202) 225–1721.

FORMATTING REQUIREMENTS:

The Committee relies on electronic submissions for printing the official hearing record. As always, submissions will be included in the record according to the discretion of the Committee. The Committee will not alter the content of your submission, but we reserve the right to format it according to our guidelines. Any submission provided to the Committee by a witness, any supplementary materials submitted for the printed record, and any written comments in response to a request for written comments must conform to the guidelines listed below. Any submission or supplementary item not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. All submissions and supplementary materials must be provided in Word or WordPerfect format and MUST NOT exceed a total of 10 pages, including attachments. Witnesses and submitters are advised that the Committee relies on electronic submissions for printing the official hearing record.

2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. All submissions must include a list of all clients, persons, and/or organizations on whose behalf the witness appears. A supplemental sheet must accompany each submission listing the name, company, address, telephone and fax numbers of each witness.

Note: All Committee advisories and news releases are available on the World Wide Web at *http://waysandmeans.house.gov*.

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202–225–1721 or 202–226–3411 TTD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

———————

Chairman JOHNSON. Good afternoon, everyone. Welcome to this hearing on health information technology (IT).

I am pleased today to chair the fourth in a series of hearings this Subcommittee has held on the subject of IT in the health care sector. Greater use of IT has the potential to dramatically improve the

safety and quality of health care for Americans while at the same time lowering costs through reductions in clinical errors, elimination of redundant procedures, improved systems capability to deliver preventive care and chronic disease care, and by significantly reducing duplicative administrative procedures.

Yet, despite these benefits, widespread adoption of IT in the field of health and out in the small towns in doctors' offices has been disappointingly slow. I have long supported efforts to increase the use of IT in health care. In 2003, I introduced H.R. 2915, the National Health Information Infrastructure Act. This bill was used as a basis for the Executive order that created the Office of the National Coordinator (ONC) for Health IT, but it is time to legislate. So, last fall I introduced, along with Energy and Commerce Subcommittee on Health Chairman Deal a follow-up piece of legislation, H.R. 4157, the Health IT Promotion Act. This bill takes a straightforward approach to addressing this issue by focusing exclusively on those areas in which Congress needs to intervene in order to ensure the development of an interoperable health information system that will serve us in the future—a future in which health care protocols and pharmaceuticals will be based on a far richer and more timely integration of our national experience with care outcomes, pharmaceutical interactions, and new developments in genetics and medicine.

First, my bill codifies the ONC. This position was created by Executive order, and both President Bush and Secretary Leavitt have demonstrated extraordinary leadership in helping people understand the value of health IT to improving care quality and their commitment to building a national interoperable health IT architecture.

However, I think it is important that the ONC be codified in statute and a solid foundation built for the oversight and continued development of this infrastructure in the decades ahead. My bill also looks at what I believe are the key issues that Congress must address if health IT is going to be advanced. Current privacy and security laws at both the State and Federal levels were passed in a paper-based era without taking into account the needs of an electronic world. I believe these laws need to be reviewed, and issues that need rethinking must be crystallized. My bill sets out a process for doing so. I recognize that this is a controversial area, but I firmly believe that it is a topic that cannot be ignored. In the end, health IT gives us the ability to improve the protection of patient information while also ensuring that electronic systems function effectively. Based on productive meetings in recent weeks, I believe the potential of this section of the bill can be realized.

This bill also seeks to open up private sector sources of funds to speed adoption of health IT by allowing various providers and payors who will benefit most rapidly to provide physicians and other providers with the technology and support services to speed the dissemination of health IT. Recognizing concerns that some have expressed that a statutory exception to the Stark and anti-kickback laws could lead to captive referral relationships between donating entities and physicians, the bill sets specific limits on the type of technology that can be donated and requires a review of the impact of these exceptions after 3 years.

From many meetings regarding the challenge of dissemination, I have concluded that a statutory rather than a regulatory exception is necessary so that all parties are clear on what is permissible. I do not believe that the regulatory exception proposed by the Administration is workable, as it is by its nature a one-by-one process to reach a nationwide goal involving literally millions of providers of all types and sizes.

I strongly support congressional action in this area and urge my colleagues to question closely the witnesses we have gathered today on this topic and suggest any follow-up meetings necessary to provide them with a thorough understanding of the challenge we face in disseminating health IT.

My bill also recognizes that we cannot build a 21st century health information infrastructure on top of an outdated coding system. As we seek to improve quality reporting and develop pay-for-performance initiatives, and as we grapple with global health issues like avian flu, we must use the updated coding system known as ICD–10 that reflects modern medicine and that has been in use for years throughout the rest of the world.

I am very encouraged by the steps that the Administration has taken to engage in a public-private partnership to move the health IT agenda forward. With the establishment of the American Health Information Community (AHIC), I believe that we will see real progress in the months ahead. My bill requires AHIC to report back to Congress on its progress and further requires the Secretary to develop a strategic plan and recommendations as to a permanent governance structure that can oversee a public-private collaborative process involving all the entities to ensure the continuous improvement of the national health information infrastructure.

Today I welcome leaders who will help us understand the truly remarkable progress that has been made to date and the additional ways in which Congress can advance the health IT agenda.

First I am happy to welcome Dr. David Brailer, who was named the National Health Information Technology Coordinator through the President's 2004 Executive order. Shortly after his appointment, Dr. Brailer produced a framework for strategic action to guide the Federal Government's efforts in this area, and he has been leading the Administration's efforts to set standards and develop a certification process to increase adoption of health IT in both the public and private sectors. He has also stimulated a remarkably broad, thoughtful dialog among technical experts and seasoned providers to help us as a nation understand the dimensions of the challenge we face. A national, interoperable, secure, and robust electronic health information system will truly revolutionize patient access to quality care and deepen and enrich the patient-physician relationship. It is a challenge we must not fail to meet, and I congratulate Dr. Brailer on the leadership he has provided. I look forward to hearing in more detail of his work and the work that is being done by AHIC and what specific results we can expect to see in the coming months.

We will also hear from Lewis Morris, Chief Counsel with the Office of the Inspector General (OIG) at the Department of Health and Human Services (HHS). He will discuss the OIG's proposed exception to the anti-kickback statute for health IT.

We will conclude our first panel with Dr. Simon Cohn, Chair of the National Committee on Vital and Health Statistics (NCVHS), which is an advisory body to HHS on health IT matters. The panel recommended moving to the ICD–10 coding system back in 2003, and he will discuss how the panel arrived at that recommendation. I also believe Dr. Cohn has an important perspective to share on what NCVHS has learned over the years in its advisory capacity, and I look forward to his testimony.

On our second panel, I am pleased to welcome a distinguished group who are currently engaged in implementing health IT. First we will hear from Brent Henry, general counsel for Partners HealthCare System in Massachusetts. Mr. Henry will discuss the work that Partners has done in implementing health IT and the additional steps it hopes to take in the future. You will also discuss the role of health IT in furthering pay-for-performance initiatives.

Dr. Ken Kizer, former president of the National Quality Forum, will discuss with us the work he is doing to promote the use of electronic health records through his company, Medsphere, along with his ideas as to how to further the adoption of technology in the health care arena.

We will then hear from Joe Smith with Blue Cross Blue Shield of Arkansas, who will discuss the progress his organization has made to date in implementing health IT and what he sees as the key steps forward.

Finally, Gloryanne Bryant of Catholic Healthcare West will discuss her experiences with the new ICD–10 coding system, the importance of such a system for quality reporting purposes, and the implementation plans for conversion that her organization already has made.

I look forward to hearing from all of our witnesses, and thank you for being here with us today, and I would like to yield to my colleague, Mr. Stark.

Mr. STARK. Thank you, Madam Chair. It is good to continue our ongoing discussion about IT in the medical care field.

We must acknowledge that we have been talking about the need for a national IT system for well over a decade, and no progress has been made. I recently found a bill I wrote the year you graduated from Radcliffe, 1992, that required Federal programs to use a common, interoperable system for billing and patient records. Unfortunately, that bill did not pass, and the absence of leadership by our Federal Government since that time has given us just a hodgepodge of proprietary silos that we can only describe as a mess.

I still don't see the Federal Government taking any leadership. We are repeating our past mistakes, giving far too much room to private IT corporations to continue their age-old fights over what standards we should be using. Those people have been talking around each other for years. As a matter of fact, if you could have believed when they started this that Apple Computer would put Windows on a Mac, then they got to that long before we have ever agreed to what kind of an IT system we should have for health care.

In the meantime, the rest of us, patients and providers, have to wait to realize the potential that we all agree that a nationwide interoperable IT system would bring to us. This has got to stop. We

need a timeline for action. We need a date certain that will get the Federal bureaucrats off their butts, and we just cannot wait for a bunch of people to agree who is going to take the lead and make all the money in this.

I am still confused as to why we are not leveraging the Veterans Affairs' (VA) system. It is highly sophisticated. It supports one of the highest-quality systems in the world. The people keep telling me the government cannot do anything right, but we already have. I have heard some talk about that some of the system is based on old code, but that is easy to correct, and that is not a government job. That is something that—we could get that done in India for a low cost. So, let's see if we cannot find creative solutions, and usually we have, instead of trying to reinvent the wheel.

I want to thank Dr. Kizer for being here today to shed some light on how the commercial use of this could work in a market environment. I am pleased that Dr. Cohn is here to discuss NCVHS and what they have done to develop a standard electronic health record. Why we have to think about re-creating the work that has been done, I don't know, and it is time, it seems to me, to just say if you want to be in the Medicare Program, you start using the electronic health records that he has developed. We will change them as time goes on, but I do not see any sense that we just have to sit and fiddle around looking to reinvent that again.

The promise of a national health information infrastructure is coming closer to fruition, but whatever solution we get to, we have to agree now is not going to work. We are going to be back here having oversight, to change, to accommodate people who find they cannot use it easily. I am just suggesting let's get started. I don't think there is any partisan differences in that, but I do think we just have to drop the gavel and say enough is enough.

Strengthening our Nation's confidentiality and security remains one of my top concerns, the issue of privacy, and I hope you and I can reach agreement on that. On the Medicare fraud provisions, I would caution the Chair and Centers for Medicare and Medicaid Services (CMS) to go carefully down that path. Every time we change those laws, we thicken the regulation book, and then a bunch of sharp lawyers find 800 ways to get around it, and then we write it again. My thought is that it is difficult for me to understand, with the hospitals in here last month complaining they are all going broke and do not have enough money, now suddenly the hospitals are telling us they want to spend a lot of money to buy expensive IT equipment. I don't know where they are going to get that money, but I don't think we are getting the same story from the hospitals on the same side of the issue. My feeling would be that I certainly would be willing to figure out a way that, in the end, if it is important to the Nation and everybody benefits, we just better figure out to start out in Medicare, let's pay—let's raise the payment per procedure and say it has got to be done this way, and then they can go and buy whatever equipment they want with the extra money we give them, because I don't think there is going to be any IT fairy that is going to put that money under our pillow or the hospital pillow. I think it is so important, I agree with you, Madam Chair, but I think we better be realistic and say it is going to cost us something. I think it would be well worth it.

I cannot close without asking you if you have got a date set for our Part D hearings, but——

Chairman JOHNSON. The first week we get back.

Mr. STARK. Really?

Chairman JOHNSON. The first week we get back.

Mr. STARK. Okay. I will be back on time. Hooray. Thank you. With that wonderful news, I look forward to today's discussion.

Chairman JOHNSON. Dr. Brailer?

STATEMENT OF DAVID J. BRAILER, M.D., PH.D., NATIONAL CO-ORDINATOR FOR HEALTH INFORMATION TECHNOLOGY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. BRAILER. Thank you, Chairwoman Johnson, Mr. Stark, Members of the Subcommittee. I have submitted my written testimony, and I will just, with your consent, give some brief overview and then remarks supporting that.

I met with you in July of 2005, and at that time I laid out a lot of philosophy, the foundations, economic, clinical, technical reasons why we are doing what we are doing. We talked a lot about what we intended to do, how we would go forward.

I am happy to tell you now that I am meeting with you that we are fully underway and we have substantial progress to report. We have actions being taken that I will summarize in three areas of work: first, in our long-term infrastructure, the capacity to have a real coherent set of activities in the United States that makes our health information useful and protected; secondly, our short-term actions, to bring us all to very short-term relevance, to recognize the needs of the American population to have relief from medical errors and other issues that they face when they consume health care; and, thirdly, actions that are underway to constitute the market drivers, set the foundation for ensuring that these ideas don't just become academic ideas, but become ideas that are underway in doctors' offices and hospitals and consumers' lives and throughout the United States. I will review each one of these.

In our long-term infrastructure, our key effort has been focused on ensuring that the United States has a coherent set of information standards. We are well underway with this. We formed 6 months ago a new group called the Health IT Standards Panel, formed under American National Standards Institute (ANSI), which is one of the Nation's leading standards bodies. This group has brought together the standards organizations in the United States but, more importantly, shifted the control over this process from technical companies and vendors, to doctors, hospitals, and consumers who are focused on their end-stage needs for using information in their business process. We have shifted this effort from looking at technical issues to look at business problems, clinical problems in health care. How does a standard help a patient going to an emergency room? How does it help a doctor communicate with another one about a complicated patient?

We have given use cases, business situations, clinical problems, to this standards group to work on. This happened in March of 2006, and by May of 2006, this group has to propose standards to meet those use cases. By the end of 2006, we expect to have detailed, implementation-ready guidelines for these use cases. These

are three problems out of perhaps 40 or 50 major issues that we face as patients navigate through health care, but the process we are developing through these four not only will address some very short-term urgent ones, but give us a process going forward over the next 2 years to have a set of standards that are coherent, modern, innovative, and meet the needs of doctors and hospitals.

Our second effort is to make sure that we strengthen and improve security and privacy. We are well underway with this as well. We have formed a new entity that is called the Health Information Security and Privacy Collaboration. This is a Federal-State partnership that brings together 43 States who submitted proposals to us that we are about to award. Twenty-six of these are to State agencies that are going to be the lead agency in the States' effort to evaluate their privacy and security roles; 17 are private sector designees, regional health information organizations, or others that have been designated by that State to act on their behalf. We will have these under contract by the end of April, and each of these will be obligated to do two things: to evaluate their State-level security and privacy rules to ensure that they are ready for the digital era of medicine; secondly, to bring all of these together to get national consensus on what it is that we have to do to make sure that we are prepared to have policies that are as progressive as our technology investments.

I ask you to follow these because we have given them a broad range of output that their consensus recommendations could constitute administrative actions, statutory actions, or any other actions that they believe are necessary for States or the Federal Government to take to ensure that health information is protected at each step along the way.

We are pushing very hard on health information exchange. We have awarded contracts totaling $18.6 million to consortia of technology companies working with doctors and hospitals in local markets. There are 12 local markets, and each of them are innovating a local architecture, a local solution for sharing information, but we are bringing these together to make sure that the United States has one set of standards for a networked solution for health information sharing, and in June of 2006, just 2 months away, we expect these groups to propose their architectures to us and to begin a public dialog so that we can understand what it takes in the United States to build out the architecture to ensure that information is portable. When a patient goes to the emergency room, if they want it to, their information is there, and, if they don't want it to, it is not. When they get referred between doctors, move, when they are evacuated from a site of a disaster or some other events, we want their information to be portable but secure along the way.

Finally, we are far along in our efforts to develop certification requirements and standards for electronic health records. The final criteria for ambulatory electronic health records were published in February of 2006 through a consensus process and the Certification Commission for Health IT. In April, which is the month we are in, we are accepting applications for certification among vendors. We expect by June to have published certification results for which vendors meet the public criteria. This certification process is critical for us to have the ability to bring along all the 300 companies,

with billions of dollars of investment into the modern infrastructure that we are anticipating so we can have the synergy of all of these efforts. We are then going to follow along immediately this year with inpatient health record certification, personal health record, and architecture certification. Our goal over the next 5 years is to have all of the key elements of health IT certified using consensus-driven, public domain, multi-stakeholder criteria.

While we are developing these long-term infrastructures, we have a number of short-term actions underway, and these short-term actions are aimed to make sure that we are just not thinking great thoughts about the future, but that we are holding ourselves accountable to move directly and linearly toward impacts that can support the American public. We launched the AHIC with its first meeting on October 7th. This group is 17 members, which are eight members from the private sector, including leaders of large technology companies, doctors, hospitals, consumer advocates, privacy advocates, and leaders of the key Federal agencies—CMS, Office of Personnel Management, the Military Health System, VA—to come together under Secretary Leavitt's leadership to make consensus recommendations on what the Federal Government needs to do to have immediate results and what the private sector needs to do. This is the novel aspect of this partnership to ensure that both the public sector and the private sector are moving forward together.

We have four breakthroughs identified: biosurveillance, where we are focused in getting standardized but anonymized data to public health agencies within 24 hours; consumer empowerment, where we are focused on having registration and demographic information and a medication history being made available to patients so they can see what their drugs are and make it available to who they choose; secure messages between doctors and patients so they can communicate in a new way that is much more empowering to the patient and much more of a convenience to the physician; and portability of lab information so laboratory data can follow patients.

We expect to see tangible, real results from these actions take place in early 2007, and to that end, on May 16th the work groups that have been formed in these areas are delivering in public their recommendations for specific Federal policy actions to be taken to realize those results. Again, these will be far-ranging, including administrative actions, potential statutory actions, so we ask you to pay attention to this. These consensus recommendations are critical in our efforts to make sure that we are focused on the here and now in addition to the future.

While we are doing these, we are also looking at the market drivers. These are the things that help us achieve the results to make sure they are just not conceptualized but delivered. We are following a so-called third pathway toward health IT adoption. On the one hand, we could take mandates or requirements for government to tell the industry what to do. We fear that this would blunt innovation and the kind of clinical transformation and communications, decisionmaking, accountability that is so intrinsically part of medicine.

We, on the other hand, don't want to take a laissez-faire approach and say we hope the market does well, because it is very clear there is a market failure here and the government has pri-

mary responsibility for addressing that. This third option is using the government's purchasing power aligned with the purchasing power of those in the private sector to ensure that we put our efforts behind these innovative and transformational opportunities. We are doing this in four areas:

First, the physician self-referral exception and the anti-kickback safe harbor. Our priority here is to take urgent action and to make sure that what we do is clear and narrow, that we are linking the exceptions and the safe harbors to proven technologies that have direct benefit to consumers.

Secondly is the actions of the Office of Personnel Management. This week, the Office of Personnel Management published its carrier letter instructing health plans about what needs to be done to access Federal Employees Health Benefits Programs. This call letter included health IT capabilities, and it included how health plans are expanding their support for health IT and what the business plans are that they are pursuing for accelerating health IT adoption in the market areas they serve.

We are also pushing this through pay for performance in the 646 and 649 demos that you know so well. Also, we are continuing the beta testing of vista office electronic health records (EHR). We do see a limited role for this supporting the safety net. It has substantial testing underway and efforts to make sure that it conforms with Health Insurance Portability and Accountability Act (P.L. 104–191) (HIPAA) and with the public certification process, but subject to these hurdles, we do expect there to be a positive contribution that it can make to the Nation's solution.

As you can see, real progress is underway. We have tangible actions we are focused on and near-term results. I appreciate your efforts, your support, and your leadership so much, and thank you for the chance to update you on our work.

[The prepared statement of Dr. Brailer follows:]

Statement of David Brailer, M.D., Ph.D., Technology Coordinator, U.S. Department of Health and Human Services

Chairwoman Johnson and Members of the Subcommittee, I am Dr. David Brailer, the National Coordinator for Health Information Technology. The Office of the National Coordinator for Health Information Technology is a component of the Department of Health and Human Services (HHS). Thank you for inviting me to testify today on health information technology activities underway in the Department.

Setting the Context

On April 27, 2004, the President signed Executive Order 13335 (EO) announcing his commitment to the promotion of health information technology (IT) to improve efficiency, reduce medical errors, improve quality of care, and provide better information for patients and physicians. In particular, the President called for widespread adoption of electronic health records (EHRs) within 10 years so that health information will follow patients throughout their care in a seamless and secure manner. Toward that vision, the EO directed the Secretary of HHS to establish within the Office of the Secretary the position of National Coordinator for Health Information Technology, with responsibilities for coordinating Federal health information technology (health IT) programs with those of relevant executive branch agencies, as well as coordinating with the private sector on their health IT efforts. On May 6, 2004, I was appointed to serve in this position.

On July 21, 2004, during the Department's Health IT Summit, we published the "Strategic Framework: The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care," (The Framework). The Framework outlined an approach toward nationwide implementation of interoperable EHRs and in it we identified four major goals. These goals are: 1) inform clinical

practice by accelerating the use of EHRs, 2) interconnect clinicians so that they can exchange health information using advanced and secure electronic communication, 3) personalize care with consumer-based health records and better information for consumers, and 4) improve public health through advanced bio-surveillance methods and streamlined collection of data for quality measurement and research.

Building on the EO, The Framework, and input received from the public and private sectors, we have developed the clinical, business, and technical foundations for the HHS health IT strategy. Let me turn to some of those now.

The Clinical Foundation: Evidence of the Benefits of Health IT

We believe that health IT can save lives, improve care, and improve efficiency in our health system. Five years ago, the Institute of Medicine (IOM) estimated that as many as 44,000 to 98,000 deaths occur each year as the result of medical errors. Health IT, through applications such as computerized provider order entry can help reduce medical errors and improve quality. For example, studies have shown that adverse drug events have been reduced by as much as 70 to 80% by targeted programs, with a significant portion of the improvement stemming from the use of health IT.

Every primary care physician knows what a recent study in the Journal of the American Medical Association (JAMA) showed: that clinical information is frequently missing at the point of care, and that this missing information can be harmful to patients. That study also showed that clinical information was less likely to be missing in practices that had full electronic records systems. Patients know this too and are taking matters into their own hands. A recent survey by the Agency for Health Care Research and Quality (AHRQ) with the Kaiser Family Foundation and the Harvard School of Public Health found that nearly 1 in 3 people say that they or a family member have created their own set of medical records to ensure that their health care providers have all of their medical information.

Current analyses examining whether health IT will produce cost savings show mixed results. Some researchers estimate that savings from the implementation of health IT and corresponding changes in care processes could range anywhere from 7.5 to 30 percent of overall health care costs. These estimates are based in part on the reduction of obvious errors. For example, on average, a medical error is estimated to cost about $3,700 in 2003 dollars. But, these savings are not guaranteed through the simple acquisition of health IT. If poorly designed or implemented, health IT will not bring these benefits, and in some cases may even result in new medical errors and potential costs (Koppel et al. 2005).

Therefore, achieving cost savings requires a much more substantial transformation of care delivery that goes beyond simple error reduction and the use of health IT. Health IT must be combined with real process change in order to see meaningful improvements in our delivery system. It requires the industry to follow the best diagnostic and treatment practices everywhere in the nation. For example, cholesterol screenings can lead to early treatment, which in turn can reduce the risk for heart disease. Where that has been done, there have been substantial savings on cardiac expenditures. Studies also show that while most investments in health IT are made by providers, consumers and payers are most likely to reap the benefits and efficiencies from these investments.

Business Foundation: The Health IT Leadership Panel Report

Recognizing that the healthcare sector lags behind most other industries in its investment in IT, HHS employed a contractor, the Lewin Group, to convened a Health IT Leadership Panel to help understand how IT has transformed other industries and how, based upon their experiences, it can transform the health care industry.

The Leadership Panel was comprised of nine CEOs from leading companies that purchase large quantities of healthcare services for their employees and dependents and that do not operate in the healthcare business. These included CEOs from FedEx Corporation, General Motors, International Paper, Johnson Controls, Target Corporation, PepsiCo, Procter and Gamble, Wells Fargo, and Wal-Mart Stores. The business leaders were called upon to evaluate the need for investment in health information technology and the major roles for both the government and the private sector in achieving widespread adoption and implementation. Based upon their own experiences using IT to reengineer their individual businesses—and by extension, their industries—the Leadership Panel concluded that investment in interoperable health IT is urgent and vital to the broader U.S. economy due to rising health care demands and business interests.

As explained by the Lewin Group, The Leadership Panel unanimously agreed that the federal government must begin to drive change before the private sector would become fully engaged. Specifically, the Leadership Panel concluded:

- Potential benefits of health IT far outweigh manageable costs.
- Health IT needs a clear, broadly motivating vision and practical adoption strategy.
- The federal government should provide leadership, and industry will engage and follow. Lessons of adoption and success of IT in other industries should inform and enhance adoption of health IT.
- Among its multiple stakeholders, the consumer—including individual beneficiaries, patients, family members, and the public at large—is key to adoption of health IT and realizing its benefits.
- Stakeholder incentives must be aligned to foster health IT adoption.

The Leadership Panel identified as a key imperative that the Federal government should act as leader, catalyst, and convener of the nation's health information technology effort. Private sector purchasers and health care organizations can and should collaborate alongside the federal government to drive adoption of health IT. In addition, The Leadership Panel members recognized that widespread health IT adoption may not succeed without buy-in from the public as health care consumer. Panelists suggested that the national health IT vision must be communicated clearly and directly to enlist consumer support for the widespread adoption of health IT.

The Technical Foundation: Public Input Solicited on Nationwide Network

HHS published a Request for Information (RFI) in November 2004 that solicited public input about whether and how a Nationwide Health Information Network (NHIN) could be developed. This RFI asked key questions to guide our understanding around the organization and business framework, legal and regulatory issues, management and operational considerations, standards and policies for interoperability, and other considerations.

We received over 500 responses to the RFI. These responses have yielded one of the richest and most descriptive collections of thoughts on interoperability and health information exchange that has likely ever been assembled in the U.S. As such, it has set the foundation for actionable steps designed to meet the President's goal.

Among the many opinions expressed by those supporting the development of a NHIN, the following concepts emerged:

- A NHIN should be a decentralized architecture built using the Internet, linked by uniform communications and a software framework of open standards and policies.
- A NHIN should reflect the interests of all stakeholders. A governance entity composed of public and private stakeholders should oversee the determination of standards and policies.
- A NHIN should provide sufficient safeguards to protect the privacy of personal health information.
- Incentives may be needed to accelerate the deployment and adoption of a NHIN.
- Existing technologies, federal leadership, and certification of EHRs will be the critical enablers of a NHIN.
- Key challenges to developing and adopting a NHIN included: the need for additional and better refined standards; addressing privacy concerns; accurately verifying patients' identity; and addressing discordant inter- and intra-state laws regarding health information exchange.

Key Actions

Building on these steps, two critical challenges to realizing the President's vision for health IT are being addressed: a) interoperability and the secure portability of health information, and b) electronic health record (EHR) adoption. Interoperability and portability of health information using information technology are essential to achieving the industry transformation goals sought by the President. Further, the gap in EHR adoption between large hospitals and small hospitals, between large and small physician practices, and among other healthcare providers must be addressed. This adoption gap has the potential to shift the market in favor of large players who can afford these technologies, and can create differential health treatments and quality, resulting in a quality gap.

To address these challenges, HHS is focusing on several key actions: harmonizing health information standards; promoting the certification of health IT products to assure consistency with standards; addressing variations in privacy and security policies that can pose challenges to interoperability; and developing a prototype, nationwide, Internet-based architecture for sharing of electronic health information. These efforts are inter-related, and a new federal advisory committee, the American

Health Information Community (the Community), will make recommendations regarding the government's role in responding to these challenges.

American Health Information Community

On July 14, 2005, Secretary Leavitt announced the formation of a national public-private collaboration, the American Health Information Community, a public-private body formed pursuant to the Federal Advisory Committee Act. The Community has been formed to facilitate the transition to electronic health records in a smooth, market-led way. The Community is providing input and recommendations to the Secretary on use of common standards and how interoperability among EHRs can be achieved while assuring that the privacy and security of those records are protected. On September 13, 2005, Secretary Mike Leavitt named the Community's 17 members, including nine members from the public sector and eight members from the private sector.

At its November 29, 2005 meeting, the Community formed workgroups that will make recommendations for specific achievable near-term results in the following areas:

- Biosurveillance—Enable the transfer of standardized and anonymized health data from the point of health care delivery to authorized public health agencies within 24 hours of its collection.
- Consumer Empowerment—Make available a consumer-directed and secure electronic record of health care registration information and a medication history for patients.
- Chronic Care—Allow the widespread use of secure messaging, as appropriate, as a means of communication between doctors and patients about care delivery.
- Electronic Health Records—Create an electronic health record that includes laboratory results and interpretations, that is standardized, widely available and secure.

These workgroups will make recommendations at the May 16 meeting of the Community.

In addition to the formation of the Community, HHS has issued contracts, the outputs of which will serve as inputs for the Community's consideration. Specifically, these contracts focus on the following major areas:

Standards Harmonization

HHS awarded a contract to the American National Standards Institute, a non-profit organization that administers and coordinates the U.S. voluntary standardization activities, to convene the Health Information Technology Standards Panel (HITSP). The HITSP brings together U.S. standards development organizations and other stakeholders. The HITSP is developing and implementing a harmonization process for achieving a widely accepted and useful set of health IT standards that will support interoperability among health care software applications, particularly EHRs.

Today, the standards-setting process is fragmented and lacks coordination and specificity, resulting in overlapping standards and gaps in standards that need to be filled. We envision a process where standards are identified and developed around real-world scenarios—i.e., around use cases or breakthroughs. A "use case" is a technology term to describe how we can focus standardization efforts on specific areas that demonstrate clinical and business value. As of March 2006 we have three common use cases for the standards harmonization process and which will be used in the other contracts discussed below. In May 2006, the HITSP will have proposed "named standards" for the three use cases. After the named standards are recommended to the Community, the HITSP will begin the development of interoperability specifications for each.

Compliance Certification

HHS awarded a contract to the Certification Commission for Health Information Technology (CCHIT) to develop criteria and evaluation processes for certifying EHRs and the infrastructure or network components through which they interoperate. CCHIT is a private, non-profit organization established to develop an efficient, credible, and sustainable mechanism for certifying health care information technology products. The contract, currently scheduled for a three-year period, will address three areas of certification: ambulatory electronic health records, inpatient electronic health records, and the infrastructure components through which they could interoperate.

The CCHIT has made significant progress toward the certification of ambulatory electronic health records. In February 2006, CCHIT began using its final criteria to conduct ambulatory electronic health record certification pilot tests and will be ac-

cepting applications for operational certification in April 2006 [note that we are now in April 2006, so this might need some clarification], with the goal of having certified electronic health record products in the marketplace as early as June 2006. Certification will help buyers of HIT determine whether products meet minimum requirements, which include functionality and interoperability.

NHIN Architecture

HHS has awarded contracts totaling $18.6 million to four consortia of health care and health information technology organizations to develop prototype architectures for the Nationwide Health Information Network (NHIN). The four consortia will move the nation toward the President's goal of personal electronic health records by creating uniform architecture for health care information. The NHIN architecture will be coordinated with the work of the Federal Health Architecture and other interrelated infrastructure projects. The goal is to develop real solutions for nationwide health information exchange by stimulating the market through a collaborative process and the development of network functions. In June 2006, the contractors will submit proposed architecture requirements for the NHIN's to HHS and a public meeting will be held to review them.

Security and privacy

HHS awarded a contract to RTI International in association with the National Governors Association Center for Best Practices. Through this contract, stakeholders, including consumers, within and across up to 40 states will assess variations in organization-level business policies and State laws that affect health information exchange; identify and propose practical solutions for addressing such variation that will comply with privacy and security requirements in applicable Federal and State laws; and develop detailed plans to implement identified solutions.

All State and territory governors have been invited to submit a proposal for participation. Proposals for participation were due March 1, 2006, and are presently being reviewed. States and territories that receive an award will be required to undertake certain activities that include: examining privacy and security policies and business practices regarding electronic health information exchange; convening and working closely with a wide range of stakeholders in the State, including consumers, to identify best practices, barriers and solutions; and developing an implementation plan for solutions to address organization-level business practices and State laws that affect privacy and security practices for interoperable health information exchange.

In the next six months, state consortia will produce an interim assessment of current privacy and security variations. To do this, state subcontractors will form collaborative workgroups to define this preliminary landscape. State solutions and implementation plans under this contract will be finalized in early 2007.

EHR Adoption Study

To assess progress toward the President's goal for EHR adoption, we must be able to measure the rate of adoption across relevant care settings. To date, several health care surveys have queried health care providers such as individual physicians, physician group practices, community health centers, and hospitals on their use of EHRs in an effort to estimate an overall "EHR adoption rate." These surveys indicate an adoption gap; however, the surveys and what they have measured have varied. These variations occur from survey factors such as the type of entity, geography, provider size, type of health information technology deployed, how an EHR is defined, the survey sampling frame methodology (e.g., the source list of physicians), and survey data collection method (i.e., phone interview, mail questionnaire, internet questionnaire, etc.).

Due to the variations in the purpose and approach, these surveys have yielded varying methods of EHR adoption measurement. In particular, no single approach yields a reliable and robust long-term indicator of the adoption of interoperable EHRs that could be used for (1) bench marking progress towards meeting the President's EHR goal and (2) informing Federal policy decisions that would catalyze progress towards reaching this goal. Therefore, HHS awarded a contract to the George Washington University and Massachusetts General Hospital Harvard Institute for Health Policy to support the Health IT Adoption Initiative. The new initiative is aimed at better characterizing and measuring the state of EHR adoption and determining the effectiveness of policies to accelerate adoption of EHRs and interoperability.

Federal Health Architecture

Now that HHS has established an infrastructure to address standards harmonization, compliance certification, nationwide health information network architecture,

security and privacy, and EHR adoption measurement through its contracts, there is a need to gain the Federal perspective in these and other Federal health information technology areas. To accomplish this, we are looking to the Federal Health Architecture (FHA), an OMB line of business, established on March 22, 2004 and managed by ONC to create interoperability and increase efficiency within the public sector. To better meet the President's health IT goals, FHA as of March 2006 has been realigned to provide the federal perspective using the processes created within ONC to ensure that interoperability exists within and between the public and private sector. FHA will achieve this refined vision by providing input into the established infrastructure and guidance for implementation within the public sector. Moving forward, FHA will be representing and coordinating the federal activities in all matters relating to the President's health IT plan.

Conclusion

Thank you for the opportunity to update you on the progress we are making in the area of health information technology. HHS, under Secretary Leavitt's leadership, is giving the highest priority to fulfilling the President's commitment to promote widespread adoption of interoperable electronic health records, and it is a privilege to be a part of this transformation.

This concludes my prepared statement. I would be pleased to answer any questions.

Chairman JOHNSON. Thank you very much, Dr. Brailer. Mr. Morris?

STATEMENT OF LEWIS MORRIS, CHIEF COUNSEL TO THE INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. MORRIS. Good afternoon, Madam Chairman and Members of the Subcommittee. I am Lewis Morris, Chief Counsel at the U.S. Department of Health and Human Services Office of Inspector General. I appreciate the opportunity to discuss the OIG's proposed safe harbors under the Federal anti-kickback statute for certain arrangements involving electronic health records.

Let me begin by stressing that the OIG and the Inspector General share Secretary Leavitt's commitment to fostering the widespread use of health IT. In furtherance of this goal, the OIG has sought to lower perceived barriers to the adoption of this technology by proposing safe harbors to the Federal anti-kickback statute.

The process of crafting these particular safe harbors requires the OIG to balance the goals of advancing the use of health IT with the objective of this important criminal statute: the elimination of potential financial conflicts of interest in the Federal health care programs. We are in the process of developing rules that we believe will strike an appropriate balance.

The Federal anti-kickback statute reflects the congressional determination that determining potential financial conflicts of interest from the Federal health care programs will help ensure Federal health care decisionmakers are not tainted by inappropriate financial influence. Financial incentives linked to referrals create risks of over utilization, increased costs to the Federal programs, corruption of medical decisionmaking, and unfair competition for providers that cannot or will not pay similar incentives.

Providing free goods and services to referral sources presents a heightened risk of fraud and abuse. In our experience, arrangements that reduce overhead—such as free equipment—or adminis-

trative expenses—such as free support staff—provide a clear economic benefit to the recipient and, therefore, can be a kickback. The risk of abuse grows as the value of the free goods and services increases. Simply put, if one purpose of the provision of free health IT is to reward referrals of Federal health care business, the anti-kickback statute is implicated.

Notwithstanding these integrity concerns, the use of health IT promises to reduce medical errors, improve quality of care, and provide better information for patients and physicians. Accordingly, Congress directed the issuance of a limited safe harbor for donations of IT necessary and used solely for the electronic prescribing of drugs. The safe harbor parameters established by Congress evidence a careful balancing of the policy goal of promoting health IT with the need to prevent fraud and abuse.

However, industry stakeholders express some concern that a safe harbor limited to electronic prescribing technology would be neither useful nor practical. In response to this call for broader safe harbor protection, the OIG proposed two additional safe harbors for electronic health record arrangements.

In developing these proposals, we undertook to balance the interests of promoting this important technology with the need to protect the Federal health care programs from abuse. As part of this analysis, we proposed factors that, taken together, would likely sever any link between remuneration and referrals. In other words, we tried to construct a safe harbor that would prevent the very conduct Congress had identified as unlawful—payment for referrals.

Let me describe in one fell swoop the measures we propose: a cap on aggregate value of the donated technology; a definition of EHR that would require it to be the core function of the technology; an anti-solicitation provision—in other words, recipients cannot shop their business; a requirement that arrangements between donor and recipient be transparent; restrictions on links to the value or volume of referrals; and interoperability.

We are currently evaluating which combination of safeguards will be most effective. For example, we are considering allowing some flexibility in the selection of recipients if IT interoperability could be ensured. Our next step will be to finalize the electronic health record safe harbor, and ultimately our goal is to harmonize two essential public policies: fostering the widespread adoption of beneficial electronic health record systems, and preventing fraud and abuse in the Federal health care programs.

This concludes my prepared remarks. I would be pleased to answer questions you may have.

[The prepared statement of Mr. Morris follows:]

Statement of Lewis Morris, Chief Counsel to the Inspector General, U.S. Department of Health and Human Services

Good morning Madam Chairman and Members of the Subcommittee. I am Lewis Morris, Chief Counsel at the U.S. Department of Health and Human Services' Office of Inspector General (OIG). I appreciate the opportunity to discuss OIG's proposed safe harbors under the Federal anti-kickback statute for certain arrangements involving electronic health records technology.

The process of crafting these particular safe harbors requires OIG to balance the policy goal of advancing the use of health information technology with the objective of this important criminal statute: the elimination of potential financial conflicts of

interest in the Federal health care programs. Working collaboratively with our government partners and considering the many constructive comments we received from industry stakeholders, we are in the process of developing rules that we believe will strike an appropriate balance.

Let me begin by stressing that the Inspector General shares Secretary Leavitt's commitment to the goal of fostering patient safety, quality of care, and efficiency in the delivery of health care through better and more widespread use of health information technology. Fully interoperable electronic health records systems will ensure that all patients will reap the benefits of the technology no matter where they receive their care. The promotion of this technology, including electronic health records, is among Inspector General Levinson's top priorities. In furtherance of this goal, OIG sought to lower perceived barriers to the adoption of health information technology by proposing anti-kickback safe harbors that would promote the adoption of open, interconnected, interoperable electronic health records systems, while safeguarding against undue risks of fraud and abuse.

Mindful that there are many possible approaches to such a safe harbor, we sought extensive public input on all aspects of our proposed rulemaking. The proposed safe harbors were published in the *Federal Register* on October 11, 2005 (70 Fed. Reg. 59015), and we received over 70 comments from hospitals, health systems, and other stakeholders. The safe harbors, if finalized, would protect certain arrangements under which hospitals and other specified donors furnish physicians and other specified recipients with free or below-market value electronic health records software and related training services.

My testimony begins with a summary of the Federal anti-kickback statute and a discussion of our longstanding concerns about arrangements involving the provision of free or reduced cost goods or services to potential referral sources. I will then discuss the provisions of our proposed safe harbor. I will not be addressing the proposed rulemaking developed by the Centers for Medicare & Medicaid Services (CMS) to create a comparable exception under section 1877 of the Social Security Act (the Act), commonly known as the "Stark" law. However, I assure you that we worked closely with CMS to ensure as much consistency between the two proposed rulemakings as possible, given the differences in the underlying statutes. It is our intent for the final rules to be similarly consistent. I am not in a position to represent the views of the Department of Justice, which has separate law enforcement authority for the Federal anti-kickback statute.

THE ANTI-KICKBACK STATUTE AND THE RISKS POSED BY FREE GOODS AND SERVICES

The Federal anti-kickback statute is one of several statutes that, broadly speaking, seek to eliminate potential financial conflicts of interest from the Federal health care programs so that health care decisionmaking is untainted by inappropriate financial influence. Our Federal health care programs, including Medicare and Medicaid, rely on physicians and others to order or select only medically necessary items and services and to refer patients to providers, suppliers, and products based on the patients' best medical interests. Financial incentives linked to referrals create risks of, among other problems, over-utilization of items or services, increased costs to the Federal programs, corruption of medical decisionmaking, and unfair competition.

The anti-kickback statute, section 1128B(b) of the Act, is a criminal statute that prohibits the knowing and willful offer, solicitation, payment, or receipt of remuneration to induce or reward the referral of any business payable by a Federal health care program. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. The statute has been interpreted to cover any arrangement where *one* purpose of the remuneration is to induce or reward referrals. Parties that violate the statute may be subject to criminal, civil, or administrative penalties. OIG has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor. Compliance with a safe harbor is voluntary, and failure to fit squarely in a safe harbor does not mean an arrangement is *per se* unlawful. Rather, the arrangement must be evaluated on a case-by-case basis under the anti-kickback statute.

OIG enforces the anti-kickback statute in partnership with the Department of Justice. Unscrupulous parties pay kickbacks in a variety of ways, and these schemes evolve over time. Often kickbacks are disguised as otherwise legitimate payments or are hidden in business arrangements that appear, on their face, to be appro-

priate. In our experience, the provision of free or below-market goods or services to actual or potential referral sources (whether physicians or other individuals and entities) presents a heightened risk of fraud and abuse. Simply put, the free or reduced price goods or services may be used as a vehicle to disguise an unlawful payment for referrals of Federal health care program business. Because physicians are effectively the gatekeepers for a substantial amount of Federal health care dollars, the programs and their beneficiaries are placed in jeopardy when a physician's ability to perform this crucial role is potentially corrupted by the inappropriate influence of a kickback. This risk grows as the value of the free goods and services increases.

Recent kickback cases have involved referral payments in the form of free office space, free equipment, free office personnel, free drugs or other supplies, inflated or sham consulting contracts, and travel and entertainment to physicians by hospitals, pharmaceutical companies, and laboratories. In our enforcement experience, arrangements that result in avoided overhead expenses (such as, free support staff, free rent or equipment, or reduced administrative expenses) can form the basis of a kickback. These arrangements provide a clear economic benefit to the recipient in the form of savings. Unfortunately, the illegal use of free goods and services to reward referrals has a long history. For example, we addressed the issue of free computers to potential referral sources in the preamble to the original final safe harbors published in 1991. The preamble states:

In some cases the computer can only be used as part of a particular service that is being provided, for example, printing out the results of laboratory tests. In this situation, it appears that the computer has no independent value apart from the service that is being provided and that the purpose of the free computer is not to induce an act prohibited by the statute. . . . In contrast, sometimes the computer that is given away is a regular personal computer, which the physician is free to use for a variety of purposes in addition to receiving test results. In that situation the computer has a definite value to the physician, and, depending on the circumstances, may well constitute an illegal inducement. 56 Fed. Reg. 35952, 35978 (July 29, 1991).

We have provided similar guidance with respect to, for example, the provision of free phlebotomists and testing supplies by laboratories to physician offices. Similarly, the provision of free or below-market electronic health records technology by a hospital to a physician in the position to refer Federal program business, depending on the circumstances, could violate the statute.

THE MMA SAFE HARBOR

In connection with the new Part D outpatient prescription drug program, in section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Congress directed the issuance of a limited safe harbor under the anti-kickback statute for donations by specified donors to specified recipients of hardware, software, or information technology and training services "necessary and used solely" for the electronic prescribing of drugs. The safe harbor parameters established by Congress evidence a careful balancing of the policy goal of promoting electronic prescribing with the need to prevent fraud and abuse. We have proposed a safe harbor for electronic prescribing technology, as mandated by Congress.

Hospital and other industry stakeholders, as well as government policymakers, expressed a concern that a safe harbor limited to electronic prescribing technology would be neither useful nor practical. They asserted that advancing the goals of increased patient safety and quality and better efficiency in health care delivery would require corresponding safe harbor protection for free or below-market electronic health records technology. These stakeholders expressed the view that without broader safe harbor protection for donations of electronic health records technology, hospitals and others would not provide free or very low cost electronic health records systems to physicians in their service areas.

THE OIG'S PROPOSED SAFE HARBOR FOR ELECTRONIC HEALTH RECORDS SOFTWARE AND RELATED TRAINING SERVICES

In response to the call for broader safe harbor protection, OIG proposed two additional safe harbors for electronic health records arrangements and solicited comments on how to balance the goal of promoting the adoption of electronic health records with the objectives of the anti-fraud statutes. As I have explained, the provision of free electronic health records technology poses all the usual risks associated with the provision of free goods and services to referral sources. If one purpose of the provision of free or below-market priced hardware, software or technical support is to induce or reward referrals of Federal health care program business, the anti-kickback statute is implicated. Moreover, there is a risk that a donor will use offers

of free technology to induce recipients to change loyalties from other providers or plans to the donor. Notwithstanding the potential for abuse, in the interest of advancing the important public policy objective of widespread adoption of electronic health records, OIG proposed two safe harbors for arrangements involving electronic health records software and related training services: one to apply before the Secretary adopts interoperability standards and one to apply after. Dr. David Brailer is here today, and he is better able to discuss these standards in detail. I am going to focus my remarks on the proposed "post-interoperability" safe harbor, because that proposal appears to be of greater interest and relevance to industry and government stakeholders.

In developing the proposed safe harbor, OIG sought to propose conditions that would create a balance between protecting beneficial arrangements while safeguarding against the undue risk of fraud and abuse. As described in more detail in the notice of proposed rulemaking, the proposed safe harbor would protect donations of electronic health records software and related training services, provided that the protected software includes an electronic prescribing component. The proposed safe harbor would require that the software be essential to and used solely for the transmission, receipt, and maintenance of patients' electronic health records and electronic prescription information. We also solicited comments on whether additional software applications should be protected if electronic health records and electronic prescribing remain core functions. We would not protect donations of technology that is used by a recipient solely to conduct personal business or business unrelated to the recipient's medical practice, because there would be a high risk of abuse and no promotion of electronic health records adoption.

The proposed safe harbor would protect the same donors and recipients that Congress included in the MMA safe harbor for electronic prescribing arrangements. Accordingly, protected arrangements would be limited to: (1) hospitals donating to members of their medical staffs, (2) group practices donating to members of the practice, and (3) prescription drug plan sponsors and Medicare Advantage organizations donating to network pharmacists and pharmacies and to prescribing health care professionals. We believe these entities are the appropriate focus for safe harbor protection because they have a direct and primary patient care nexus, they play a central role in the health care delivery infrastructure, and they are well-positioned to promote widespread use of electronic health records technology that is open and interoperable. Notwithstanding, we solicited public comment on whether other donors and recipients should be included in this safe harbor.

To promote the objectives of an interoperable health records system, the proposed safe harbor would require that protected software be certified in accordance with product certification criteria for interoperability adopted by the Secretary. We believe that donations of technology that meets uniform interoperability standards for electronic health records adopted by the Secretary, as well as product certification criteria to ensure that products meet those standards, will help preclude unscrupulous donors from using closed or isolated systems to tie recipients to particular providers or suppliers. In light of the enhanced protection against some types of fraud and abuse that would be offered by certified, interoperable systems, we indicated that we are considering giving donors some additional flexibility in selecting recipients of the technology. Specifically, we indicated that we are considering permitting donors to use selective criteria for choosing recipients, provided that neither the eligibility of a recipient, nor the amount or nature of the items or services provided, is determined in a manner that *directly* takes into account the volume or value of referrals or other business generated between the parties. Examples of criteria that would be appropriate under this proposed condition might include a determination based on the total number of hours that the recipient practices medicine or the size of the recipient's medical practice. Consistent with our objective of minimizing the risk of abuse, donors could not select recipients based on the number or value of Medicare-payable items or services referred to the donor. We expect that this approach would allow donated electronic health records technology to be provided to recipients most likely to use it, without protecting problematic direct correlations with referrals.

This approach to selective criteria, if adopted, would be a deliberate departure from other safe harbors that prohibit any determinations that take into account, directly or indirectly, potential referrals or other business generated between the parties. This proposed approach responds to the unique policy considerations surrounding electronic health records systems and the Department's goal of encouraging their adoption. Outside the context of electronic health records, as specifically addressed in the proposed rule, both direct and indirect correlations with Federal health care business remain highly problematic under the anti-kickback statute.

Finally, to reduce the risk of fraud and abuse, we indicated that we are considering capping or other otherwise limiting the aggregate value of the donated technology. In this regard, we solicited public comment on a range of possible options for structuring such a limit, as well as on the retail and nonretail costs of the technology. We also indicated that we would require full transparency of arrangements through complete and appropriate documentation.

CONCLUSION

It is important that any safe harbor for electronic health records arrangements promote open, interconnected, interoperable electronic health records systems that help improve the quality of patient care and efficiency in the delivery of health care to patients, without protecting arrangements that serve to influence inappropriately clinical decisionmaking or tie physicians or other referral sources to particular providers or suppliers. We were mindful as we drafted the proposed rulemaking that there are several possible approaches to this safe harbor and that we did not have full information on all relevant aspects of such arrangements. For that reason we used the rulemaking solicitation as a platform to solicit public comments on virtually all aspects of the proposed rulemaking. The health care stakeholders responded by providing substantive comments on a wide range of issues. We are in the process of reviewing and considering those comments and evaluating options for the final rulemaking. Ultimately, our goal is to achieve an appropriate balance between fostering the adoption of beneficial electronic health records systems and preventing fraud and abuse in the Federal health care programs.

This concludes my prepared statement. I would be pleased to answer any questions you or Members of the Subcommittee may have.

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Chairman JOHNSON. Thank you very much, Mr. Morris. Dr. Cohn?

STATEMENT OF SIMON P. COHN, M.D., CHAIRMAN, NATIONAL COMMITMENT ON VITAL AND HEALTH STATISTICS, OAKLAND, CALIFORNIA

Dr. COHN. Good afternoon, Chairwoman Johnson, Congressman Stark, and distinguished Members of the Subcommittee. I am Dr. Simon Cohn, Chairman of the National Committee on Vital and Health Statistics. The National Committee is the statutory Federal advisory Committee to the Secretary of HHS on health information policy, including data standards and privacy issues. I am also the Associated Executive Director for the Permanente Federation of Kaiser Permanente. Kaiser Permanente is the Nation's largest integrated, nonprofit health care organization, serving the needs of 8.4 million members.

I am testifying today in my capacity as NCVHS Chairman. All of the information I will be discussing today is available on the NCVHS website.

This afternoon, I will talk briefly about the role and history of the National Committee, then focus hopefully most of the time on experience and lessons learned relating to the adoption of national health data standards, including some thoughts about how we can accelerate the standards process, and then finish with thoughts on current national IT and data standards initiatives.

The NCVHS has a long and distinguished history. In recent years, Congress has directed the National Committee to play an important consensus development and advisory role in data standards, initially in HIPAA and more recently in the Medicare Modernization Act for e-prescribing.

My written testimony includes recent accomplishments and reports related to the topics under discussion today. I do, however, want to briefly highlight two pieces of work.

First, in 2001, our report "Information for Health" sets forth a vision and framework for interoperable health IT. The report recommended and foreshadowed many of the initiatives we are very excitedly seeing underway today, including the creation of an office to provide leadership and coordination reporting directly to the Secretary. This idea was later reflected in the establishment of the ONC.

Second, the NCVHS report "Uniform Data Standards for Patient Medical Records Information" sets forth a strategy, framework, and criteria for selection of clinical data standards. This strategy provided the foundation for the selection of clinical message format standards and clinical terminology standards that became the core of the Federal Consolidated Health Informatics Initiative. Now, this work has provided important standards guidance and has been an important input into the work of ONC and the various health IT acceleration initiatives underway.

With that, let me turn to our observations and lessons learned related to the adoption of national health standards, specifically as it relates to HIPAA and e-prescribing.

With regards to the HIPAA data experience, there are several observations I would like to make. First and foremost, HIPAA implementation has clearly taken longer than anyone expected. Congress had expected an 18-month period to identify standards, followed by a 2-year implementation, followed by routine and frequent updates to the standards. The NCVHS for its part was able to meet its deadline for the identification of the required standards and is already working with the standards development organizations in relationship to updating of the standards. However, the actual implementation itself has been significantly drawn out. There are multiple factors that have contributed to this delay, and certainly many more than I have time to talk about today, but they do include things such as complexity and diversity of the administrative processes in health care, the sheer number of players involved, including health plans, clearing houses, and providers.

We have moved through much of this. The bigger issue now is the complexity and seeming slowness of the Federal rulemaking process, at least as it relates to HIPAA. NCVHS has noted on multiple occasions that the inability to in a timely and orderly fashion adopt and update HIPAA standards is severely hampering the ability of the health care community to keep pace with emerging business needs.

Let's now turn for a moment to compare and contrast this with e-prescribing. The NCVHS experience in recommending e-prescribing standards was quite different from that of the HIPAA process. The Medicare Modernization Act (P.L. 108–173) (MMA) provided more flexibility, and all of this testimony from the industry has highlighted a critical need for a flexible and timely standards modification process. Luckily, the MMA provided some latitude for adoption of new versions of standards. The NCVHS recommended the concept of voluntary adoption of new versions of the standards if they maintain the base functionality and data content

of previous versions, so-called backward compatibility. This approach was incorporated in the final rulemaking.

So, let me talk briefly about some of the lessons learned. First of all, an open, collaborative, consultating process that brings together the public and private sectors, such as NCVHS uses, is essential and was effective in both cases. Pilots also play a central role in road-testing new standards. Even small pilots yield valuable information that can help speed implementation and would have been helpful early on in the HIPAA process. We have recommended this for the claims attachment standard with good results, and we were delighted when this was being used for e-prescribing.

Finally, for existing standards, there is a critical need for a standards change management process that can nimbly keep up with changes in business needs. One possibility might be to apply a process like that used for e-prescribing to HIPAA, and so this could have some applicability. However, since not all standards are backward compatible, this would not represent a total solution. Another option that would have applicability to all of the HIPAA standards could be to streamline the modifications process for already adopted standards by asking NCVHS to hold open hearings on such changes and, if broadly accepted by the health care industry, recommend that HHS utilize a modified rulemaking process in these circumstances.

Now, in conclusion, let me briefly talk about the broader health IT initiatives underway and ongoing collaborations. The NCVHS is very pleased and supportive of the current interest and initiatives at the national level to accelerate the adoption of interoperable health IT, and the NCVHS is committed to help accelerate progress. In many instances, the initiatives move forward recommendations and approaches that arose initially from the work of the NCVHS, in collaboration with HHS and the industry.

I have met with Secretary Leavitt, and he was very receptive when I offered our expertise, advice, and service in support of his health IT agenda, particularly in the areas of privacy and information infrastructure. We work closely with Dr. Brailer. We include briefings for Dr. Brailer at all of our full NCVHS meetings, and NCVHS members are included as technical experts in several of the AHIC breakthrough working groups. I also meet regularly with Dr. Brailer and have offered our assistance in a variety of ways, including coordination with and complementing the AHIC and ONC initiatives.

Thank you for the opportunity to testify today about the Committee's activities related to health IT. I would be pleased to respond to any questions you or other Members may have.

[The prepared statement of Dr. Cohn follows:]

Statement of Simon P. Cohn, M.D., Chairman, National Committee on Vital and Health Statistics, Oakland, CA

Good afternoon, Madame Chairman and distinguished Members of the Subcommittee. I am Dr. Simon Cohn, Chairman of the National Committee on Vital and Health Statistics (NCVHS). The Committee is the statutory federal advisory committee to the Secretary of Health and Human Services on health data, statistics and health information policy, including data standards and privacy issues. I am also the Associate Executive Director of the Permanente Federation, Kaiser Permanente. Kaiser Permanente is the nation's largest integrated nonprofit, health care organization, serving the needs of 8.4 million members in nine states and Washington,

D.C. The Permanente Federation is the national organization of the Permanente Medical Groups, the physician component of Kaiser Permanente.

I am testifying today in my capacity as NCVHS Chairman. All of the information I will be discussing today is available on the NCVHS website at ncvhs.hhs.gov.

This afternoon, I will focus my remarks on (1) the role, history and perspective of the Committee; (2) our experience and perspectives relating to the adoption of national health data standards; (3) reflections on how the standards adoption process might be improved and accelerated; and (4) our perspectives on how the various current national health IT and data standards initiatives can work together to advance the national HIT agenda.

Role, History and Accomplishments of the NCVHS

The NCVHS has a long and distinguished history of facilitating the development of industry and government consensus on health data policy issues and data standards and providing broad based expertise and advice to the HHS and other federal health agencies. The NCVHS is established by law in section 306(k) of the Public Health Service Act and has a mandate to assist and advise the Secretary on a wide array of health care data issues. In recent years, Congress has directed the Committee to play a role in consensus development and an advisory role in data standards, initially through the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and subsequently in the Medicare Modernization Act of 2003 (MMA). The Committee's HIPAA responsibilities included advising the Secretary on data exchange standards, code set and terminology standards, privacy and security standards, and identifiers, and in MMA, on the data standards needed to support the electronic prescribing provisions of MMA. The Committee is recognized and highly regarded for its open, well established, collaborative industry public-private consultation process and its timely, thoughtful and practical recommendations.

Members of the Committee are appointed from among individuals distinguished in a wide range of health information policy areas, including health statistics, electronic interchange of health care information, privacy, security, population-based public health, purchasing or financing health care services, integrated computerized health information systems, health research, consumer health advocacy, health data standards, epidemiology, and the provision of health services. Sixteen members are appointed by the HHS Secretary, and two are appointed by the leadership of the Senate and the House of Representatives respectively. Technical experts and representatives of all stakeholders—including providers, plans, commercial interests, not-for-profit groups, governments, and consumers—provide input to NCVHS deliberations through regular, extensive public meetings.

Through its advice and recommendations, NCVHS has stimulated a host of improvements in national and international health information infrastructure, data and statistics. The Committee has been associated with contributions in disease classification, health surveys, data standards, data needs for minority and other special populations, mental health statistics, State and community health data needs, and privacy protection. While the NCVHS may be best known for its work on data standards and health information exchange, it has played a significant role in public and population focused health data issues and needs as well.

Recent accomplishments related to the topic under discussion today include:

- **Strategic Vision for Health Information Infrastructure—**The NCVHS' 2001 report, *Information for Health: A Strategy for Building the National Health Information Infrastructure,* set forth a vision and framework for interoperable health information technology (HIT). The report identified three primary dimensions that together comprise a national health information infrastructure—information to support the needs of 1) patient care, 2) population and public health, and 3) personal health. The report recommended and foreshadowed many of the accomplishments and initiatives we see underway today, including the creation of an office to provide leadership and coordination for the development of the National Health Information Infrastructure (NHII), reporting directly to the Secretary, an idea later reflected in the President's Executive Order and the HHS initiative to establish the Office of the National Coordinator for Health Information Technology in HHS.
- **Strategy for Healthcare Information Interoperability—**In 2000, the NCVHS published a report, *Uniform Data Standards for Patient Medical Records Information,* that set forth a strategy, framework, and criteria for selection of clinical data standards. This strategy provided the foundation for the selection of clinical message format standards (2002) and clinical terminology standards (2003) that have become the core of the Consolidated Health Informatics Initiative.

- **Electronic Prescribing**—The Medicare Modernization Act directed NCVHS to identify and recommend standards for e-prescribing that could be used in implementing the new Medicare Part D benefit. NCVHS accelerated its schedule of meetings and proposed an initial set of well-established standards that were later incorporated into a proposed rule. This allowed the industry to fill standards gaps and harmonize related standards in time for e-prescribing pilot tests beginning in January 2006. The process also served as a model for obtaining industry input into the regulatory process.
- **Personal Health Records**—Last September the NCVHS issued a report of findings and recommendations concerning electronic personal health records and personal health record systems. Based on six public meetings, the report describes the current heterogeneity and state of the art in PHR concepts and systems, discusses the potential roles that PHR systems could play in improving health and health care and furthering the broader HIT agenda, and sets forth 20 recommendations for moving forward.
- **Population Health**—Recommendations in the Committee's report, *Shaping a Health Statistics Vision for the 21st Century,* described a model of the influences on the population's health and established guiding principles to improve integration and coordination of health data and information used by policymakers, researchers, and the public to improve health.
- **Eliminating Health Disparities: Strengthening Data on Race and Ethnicity**—Released last November, this NCVHS report identified a number of opportunities and recommendations for improving data on race and ethnicity to help understand, measure and eliminate disparities in health and health care.
- **HIPAA Administrative Simplification Data Standards**—In HIPAA, Congress directed the Committee to assist and advise HHS in the adoption of a range of industry consensus data standards to support administrative simplification in health care. The standards included data transaction standards, code sets and terminology standards, privacy and security standards and identifiers. For the last decade, NCVHS recommendations formed much of the basis for the subsequent HHS regulations adopting the standards for use in administrative transactions in health care. NCVHS also advises HHS on HIPAA implementation progress and prepares an annual report to Congress on the progress of the HIPAA data standards initiative.

Improving and Streaming the Standard Adoption Process: Lessons Learned

Based on NCVHS experience in working with the industry and assisting and advising on the adoption of various types of data standards, several "lessons learned" have emerged for improving the overall process.

HIPAA Administrative Simplification Standards

NCVHS has advisory responsibilities for assessing the impact of the adoption and use of transactions and code sets that are ultimately adopted under the administrative simplification provisions of the HIPAA. The process starts when the various standards development organizations (SDOs) work with their membership to reach consensus on HIPAA transactions and code sets that need to be adopted or modified and those changes are brought to NCVHS for review. The Committee generally explores these recommendations through its established open meeting process. The NCVHS process ends with a recommendation letter to the Secretary of Health and Human Services based on the testimony that was provided. Further Department evaluation, based on the recommendations, usually results in the start of the required rule making process.

With regard to HIPAA data standards, there are several lessons that the Committee gleaned through the numerous meetings that have taken place since this landmark legislation was passed a decade ago. HIPAA implementation has taken longer than expected. Our explanation for this includes the complexity and diversity of administrative processes in healthcare, the number of players involved, and the complexity of the federal rulemaking process.

NCVHS testimony noted that inability to effect timely and orderly introduction, adoption and updating of HIPAA standards severely hampers the ability of the public and private sectors to keep pace with emerging needs, especially in the rapid acceleration toward the adoption of EHRs. The unpredictability of the time needed to complete all of the steps in the federal rule making process create an uncertain environment in which it is difficult for providers, payers and vendors to influence or anticipate upcoming changes and develop business products and processes to accommodate them. The inability in a timely fashion to adopt new versions of standards under HIPAA coupled with the uncertainty of the timing of changes prevents the HIPAA community from evolving to new standards that address current business

needs. The NCVHS continues to believe that the full economic benefits of Administrative Simplification will only be realized when all the standards are in place and when an orderly change management process has been successfully established.

Electronic Prescribing Data Standards

NCVHS' role and experience in recommending e-prescribing standards was entirely different from that in the HIPAA process. The MMA specified that NCVHS should develop recommendations on standards used for e-prescribing under the new Medicare Part D drug benefit. It included a fairly long list of needed standards functionality for e-prescribing. The MMA additionally specified that some of these standards could be adopted immediately after rulemaking without pilot testing if they had adequate industry experience while the remaining standards would need to be pilot tested during calendar year 2006 and subject to subsequent rulemaking.

Based on the specificity and rigorous time frames of the MMA, NCVHS had 18 months to complete its work on this emerging topic. The Committee held several meetings to understand the current e-prescribing process and identify the relevant stakeholders in order to ensure balanced testimony. NCVHS then proceeded with meetings on the existing e-prescribing environment, and identified gaps in terms of the specific standards required by the MMA and specific supporting standards needed by the industry.

The process concluded with two comprehensive recommendation letters developed in partnership with various industry groups that were sent to the HHS Secretary. NCVHS' recommendations on e-prescribing standards that could be adopted without pilot testing were adopted in a final rule in November 2005 that laid out "foundation standards" for use in Part D. NCVHS' other recommendations on standards that needed to be pilot tested were incorporated into the required pilot tests that began on January 1, 2006, as specified by the MMA.

Moving Forward and Lessons Learned

The NCVHS' open, collaborative process has repeatedly proven its effectiveness. NCVHS has served as an honest broker for a wide range of issues and stakeholders. This process has been used to provide advice and guidance on the HIPAA standards. The value of this process was especially apparent for recommendations for e-prescribing standards under the MMA, when the NCVHS identified the relevant stakeholders, brought them to the table, and broke new ground in terms of identifying standards, gaps, and workable solutions. This additionally was accomplished within the confines of tight timeframes and content requirements imposed by the statute. Because of the way NCVHS structured its process, the industry voluntarily coalesced to develop solutions that would benefit all stakeholders.

Pilot testing plays an essential role in "road-testing" new standards. Even small pilots yield valuable information that can help speed implementation.

Establishing standards for transactions does not automatically lead to complete standardization of business practices. There will always be variation, but industry efforts to reduce unnecessary variability in business rules should be encouraged.

There is a critical need for a standards change management process that can nimbly keep up with changes in business needs. One possibility might be to widely implement a process analogous to the e-prescribing voluntary adoption process, where the adoption of new versions of standards are allowed as long as they are backward compatible, for other standards, including HIPAA. However, since not all SDO standards are backwards compatible, this would not represent a total solution. Another option could be to streamline the adoption of version changes to already adopted standards by asking NCVHS to hold open meetings on such changes, and if broadly accepted by the healthcare industry, recommend that HHS utilize a modified rulemaking process in these circumstances.

Moving Forward on Data Standards and Interoperable Health Information Technology

The Committee is very pleased and supportive of the current interest and initiatives at the national level to promote and accelerate the adoption of interoperable health information technology to improve health and is both eager and committed to helping to move progress forward. In many instances, the initiatives reflect concepts and recommendations and approaches that arise directly from the productive and collaborative relationship involving the NCVHS, HHS and the industry.

To this end, I met with Secretary Leavitt last June to discuss the role that the National Committee on Vital and Health Statistics could play in supporting this agenda for improving health and health care through advances in interoperable health information technology, and I was gratified with his enthusiastic response when I offered our expertise, advice and service in support of his HIT agenda. During the inaugural meeting of the American Health Information Community, Sec-

retary Leavitt indicated that he would be relying on the NCVHS for expertise and advice on advancing the national Health Information Technology agenda, particularly on privacy and information infrastructure issues.

I have also met with David Brailer and have indicated that the Committee stands ready to assist and advise HHS in a number of ways, including coordinating with and complementing the American Health Information Community for achieving objectives ofnationwide electronic records that will result in improved health. The AHIC is currently focusing its efforts onachieving rapid breakthroughs in specific areas and achieving industry executive level interest and buy-in.

In addition, to further enhance coordination, we include briefings and updates from Dr. Brailer at all of our full committee meetings,and NCVHS members are included as technical experts on several of the AHIC breakthrough Working Groups. We are continuing to work with Dr. Brailer's office to explore additional areas for collaboration.

As I indicated to you earlier, the Committee welcomes the new roles that are possible for NCVHS with respect to working with the AHIC and the national health infrastructure agenda generally.

Conclusion

Thank you for the opportunity to testify today about the Committee's activities relating to health information technology. I would be pleased to respond to any questions that you or other Members might have.

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Chairman JOHNSON. I thank the panel, each of you, for your excellent testimony.

Dr. Cohn, I am very, very interested in this standards change management process. You do not just insert technology. Technology creates an environment of continuous improvement, and if it does not create that mental environment, that team environment, and that technological environment, you do not get the benefit of the technology. So, I think your point is very well taken, and if any of the panelists on this panel or the following panel disagree, I want to hear about it, because I want to work with you all to see if there is anything we need to do to help you to develop that ability to simply upgrade and modernize and manage the changing standards we need in technology as technology changes.

Dr. Brailer, I wanted to ask you to describe a little more in-depth this project you have gone on with the National Governors Association. We have a provision in our bill that just looks at those things, but I am interested in what you are doing and what you have laid out and what your task is to them, both in terms of the internal relation issues within a State between the State privacy rules, regulations, and statutes and so on, and electronic implementation, but also between States and with the Federal Government and difficult issues like mental health that we struggle with.

Dr. BRAILER. Well, clearly, we felt that we had primary responsibility for not letting the technical innovation and technical projects go forward in the absence of a policy framework that brought along privacy and security, and that is what motivated the project. Our particular concern was that there was a lot of debate about what was good or bad about HIPAA but not a lot of forward thinking about what does the digital era of medicine mean when information is quite free floating, regardless of what technical solution we might use, that is being made available and being much more portable.

We wanted to engage the States on this primary from the beginning because the States are the ones who have largely set the pri-

vacy tone for many of the citizens because so many States have su-
perseded the minimum requirements of HIPAA. So, what we have
done is put together Federal leaders, the government as well as
other leaders, other experts at the national level, with a represent-
ative, designees from each State—again, there are 43 States. We
had seven States who elected not to participate in this process.
They have two obligations: first, within their State, to look at their
own State laws and to begin evaluating issues in the laws, vari-
ations in the laws, holes, absences, issues that they feel are incom-
plete, and to come together and get some recommendations at the
State level about where they think there should be changes; and,
secondly, to have the States come together as a whole and begin
developing national consensus, to begin asking what does the pri-
vacy framework look like for the United States as we go forward.
I will raise a couple of examples.

First, there is a lot of discussion, as one example, about the ac-
counting rules. How does one keep track of who sees health infor-
mation, personal health information? It turns out this is an issue
that is quite contentious because of paper. It is hard to do this with
paper, and it is hard to protect it with paper. In an electronic era,
we have a new opportunity to begin moving away from that
contentiousness to say accounting should be easily part of the elec-
tronic infrastructure. It is not a cost burden on providers, it is eas-
ily practiceable, and it gives us a new level of security. So, that is
an opportunity that we want to pursue that the electronic infra-
structure brings forward.

On the other hand, there are new challenges. Many people are
talking about putting their information in a personal health record
that is an independent entity, not sponsored by their doctor or
their hospital or their health plan, or to use HIPAA-esque lan-
guage, not a covered entity. That means that that entity does not
have requirements or restrictions or regulations or penalties if they
abuse personal health information. We think that there needs to be
a look at how do we begin asking this question of bringing every-
one into the fold.

We are particularly concerned about the mental health area be-
cause so many of the States have, rightly, begun identifying mental
health-related information as protected information that should not
be made available to prevent stigma, which is an appropriate ac-
tion. On the other hand, people in the mental health community
have begun discussing with us the concerns that so many drug-
drug interactions occur around or because of mental health medica-
tions, that if we simply blunt those from being made available, if
we just say not available at all, we will create a situation for many
mental health patients where they have to choose between stigma
or death. We do not want that to happen. We want to make sure
we develop the thinking that allows us to protect that, but make
it available in some way that they do not face a dangerous drug-
drug interaction.

This group is expected to report in 9 months, to have a set of
consensus recommendations about what should be looked at, what
this should look like, what policy changes are required at the Fed-
eral level or State level, and that will be done in a public way so
all of us can look at it. I think it is the first forward-looking evalua-

tion of privacy and security as we move into this information age of health care.

Chairman JOHNSON. That is very interesting. My time has expired. I need to come back with a question about the role you see for government, if there is time, but I am going to yield to Mr. Stark.

Mr. STARK. Thank you, Madam Chair.

Dr. Cohn, how long have you been with NCVHS?

Dr. COHN. I have been a member of NCVHS since 1996.

Mr. STARK. Bingo. So, you were there in August 1996 when they came out with the report on the NCVHS with core health data elements, right?

Dr. COHN. I was just coming onto the Committee at that point.

Mr. STARK. What has changed since 1996? How would you revise these core health data elements? Pretty good still, aren't they?

Dr. COHN. Well, Mr. Stark, Congressman Stark, I will apologize, but I have to say it has been some time since I have reviewed them.

Mr. STARK. Nobody else has either, so don't feel bad.

[Laughter.]

Mr. STARK. In other words, all we are hearing today is a lot of gobbledygook today about reinventing the wheel. You guys did this—I guess what I am getting at is that I am afraid NCVHS has sort of been out of the loop here, and I am afraid that a lot of the programs we are hearing about are duplicating work that has already been completed. Is that a fair statement?

Dr. COHN. I actually do not believe that the work being done is replicating work that has already been completed. I think the role of the National Committee and much of the work that we have done has been forward thinking work and at a certain——

Mr. STARK. That was 1996. We are now——

Dr. COHN. Well, I am referring to the work of the last 10 years since I have been on the Committee, but with the issue being that it is one thing, for example, to recommend that we have implementation guides with enough specificity to ensure interoperability.

Mr. STARK. Bingo.

Dr. COHN. It is another thing to actually do it.

Mr. STARK. Well, we will get to the "do it" in a minute. First of all, Kaiser has a system now—do you believe that we should, first of all, deal with an open-source solution here so we don't have guys with proprietary ways to keep the rest of us from knowing what is going on? Have you got any objection to an open-source system?

Dr. COHN. Well, I don't think I have an objection. Wearing my hat as NCVHS, I don't think we have an opinion on it.

Mr. STARK. You don't have any objection to it.

Dr. COHN. No, certainly not.

Mr. STARK. Okay. Put your Kaiser hat on for a minute. Kaiser has a fairly elaborate and comprehensive system of electronic data recordkeeping, does it not?

Dr. COHN. Yes.

Mr. STARK. If we instigated a different system for Kaiser through some great Federal law and it was substantially different,

it would cost Kaiser a good bit of money, wouldn't it, to have to change and retrain and do everything over again, wouldn't it?

Dr. COHN. I was trying to avoid——

Mr. STARK. For any—for Blue Cross, it would be a substantial change.

Dr. COHN. Sure.

Mr. STARK. Any practicing physician, if we continue with these multiple versions, is going to have to learn several systems, won't that physician? Because Blue Cross will have a system and somebody else will have a system and Medicare will have a system, and they will have to fill it out differently unless we mandate a universal system. Does that make sense to you?

Dr. COHN. Well, I think the National Committee has taken a different view on this over the years, and——

Mr. STARK. Well, I am not as—okay, go ahead.

Dr. COHN. Okay. Well, no, I think that rather than a universal system, what we want to have is enough interoperability between systems that the data flows easily, is understandable and recognizable——

Mr. STARK. Okay. How about the core health data, those elements? Should that be universal? I can go down the list for you. If you want——

Dr. COHN. Sure.

Mr. STARK. Name or a unique identifier?

Dr. COHN. I will agree to that.

Mr. STARK. How about date of birth? That should be in all the records, shouldn't it?

Dr. COHN. Well, sure. It——

Mr. STARK. Okay. Gender, race and ethnicity? You got any——

Dr. COHN. No.

Mr. STARK. Residence, marital status, self-reported health status, functional—all of those things most people would agree to, wouldn't they?

Dr. COHN. Well, certainly.

Mr. STARK. Okay. Well, why don't we get going? Why don't we just lock that one up and say, okay, that is done? You did it in 1996. Do we have to wait another 10 years until—why are we repeating all this stuff? That is what I do not understand. Just to give a bunch of private guys who want to peddle systems a chance to have different systems? I am just afraid that your Committee has done a lot of work and it is being ignored and that we are reinventing wheels here day after day. Unless somebody says that on a day certain, January 1, 2007, it will be a Federal law that all data is collected in this manner, with an open-source system and made available in a government-run library, I am just—it will be wrong, whichever way we do it, and we will have to adjust it as we go on—it will never get done. Kaiser will go on with their system, and the University of California will go on with their system, and Health WellPoint will go on with their system, and 10 years from now they won't talk to each other.

Do you see any other alternative, unless it is mandated by—I hate to use "the Federal Government."

Dr. COHN. Let me try to address your questions, and I certainly do not have the answer to what you are describing, but I do want

to reflect—and I think at least as I talk about the work that is going on now and the work that has happened over the last 7 to 10 years, which really is, to my view, the creation of the foundational pieces of the infrastructure, which is really HIPAA, which deals not with every single data element you are talking about, but as part of the administrative and financial transaction, it does begin to set—it sets standards. Now, it does not create systems, but it creates the standards that allow systems to communicate their data back and forth in a common fashion.

So, with HIPAA, even though the process is not perfect and I think we need to fix it, we are seeing identifiers coming forward. We have seen basic privacy. We are seeing security rule. We have many of the data elements and transactions, including claims and other types of transactions. So, when I talk about——

Mr. STARK. What is missing? What do we need to get started?

Dr. COHN. Well, that is actually already working, but that does not move us really into the clinical realm.

Mr. STARK. What is needed to get us there?

Dr. COHN. Well, I think we need to have some validation that the standards are the right standards, which is, I think, the work that ONC and the initiatives are doing, which is going back looking at all the work, another validation that X standards are the right standards to work with going forward as we implement more widely.

David, you may want to join in.

Mr. STARK. Well, my question is we have got VistA and it works. Right?

Dr. COHN. Yes.

Mr. STARK. It works well. Why not use that? Could Kaiser live with it if we paid the money that you would need to convert? What would happen if patients—my in-laws in San Lorenzo, would their care be as good as it is now at Kaiser if they had VistA?

Dr. COHN. Well, can I make the following comment? I——

Mr. STARK. Sure.

Dr. COHN. First of all, unfortunately, I am probably going to meld my hats for a minute here, but I think we all think that VistA is a wonderful system and it is highly functional. The VA has made tremendous use for it, and certainly in testimony before the NCVHS and I am sure probably before you, I think we have all been impressed with what it can do. You will hear other testimony later on today, but I think as we have all evaluated it the issues get to be, to a certain extent, transportability, integration with other systems. I think as—and maybe even on a higher level, when you look at the total costs of implementation of health IT into environment, only a piece of it is the IT system. So, much of it is actually sort of dwarfed by education, training, support, all of those other things.

So, as I said, great system, but you just need to keep aware of——

Mr. STARK. That is going to happen whenever you have—Kaiser is going to get hit with that if it is not the Kaiser system, aren't they? Or WellPoint is going to get hit with it if it is the Kaiser system. Because whatever you pick, if there is a uniform system, somebody is going to have to learn a new language or a new proce-

dure. Arguably, we cannot—and if we just say, well, okay, we are going to leave Kaiser where they are and VistA where it is and WellPoint where it is, then we are not going to have the system we all think we should have. The idea that you think you are going to pick one best system I despair of. I think we are going to pick a system that, as I have said to the Chair often, will not work. We will have all kinds of complaints, and we will be up here having hearings forever, and I will not be able to have the courtesy of going over my time limit, and we will have to change it, but we could be doing it while we change it.

Thank you, Madam Chair.

Chairman JOHNSON. Mr. Stark, do notice that I have given you the courtesy of going over time.

Mr. STARK. I do appreciate it very much.

Chairman JOHNSON. Because you did ask a core question, and I think it is so important that we ought to let Dr. Brailer respond, too, because as I understand your core question, it is: What are the consequences of picking a single technology for the system? Beyond that, are we spinning our wheels? Do we already know this and we are just spinning our wheels to get a lot of companies involved in whatever? So, if Dr. Brailer would like to comment, I think it would be useful because this is a foundational question you have asked.

Dr. BRAILER. I think it is actually a good question, and it is one that we certainly spend a lot of time looking at.

I, too, share the support for the VA system, but I think the miracle of the VA system is not the software. It is the size of the VA, its scale, its ability to deliver and develop such a system, its single budget that allows it to actually look at the savings that it creates and invest those to some degree back into its systems, and the fact that it is immune from the kinds of siloing that some of the rules in the Federal Government create that allow it to act like a seamless system.

We could not just export those elements of the VA miracle to doctors and hospitals through software. We know that Kaiser is a good example, and many doctors are like this, that the challenge they face is not software. Software is the minor component of the cost they face whenever they convert over to electronic systems. It is productivity loss. It is training. It is the cost of conversion of their systems. The saying in the industry is, I think, true here: Free is not cheap enough. We cannot just give software to doctors and expect it to be the right thing for them. If we give it to them with a mandate, then I think we face the challenge that we are creating a technological obsolescence, because no system is perfect today, and we will be left with the standards or the other mechanisms that are inherent.

The approach we are taking is more organic. It is certainly one that even Britain, which I think has a health care system that some people would think is more what the United States should have, is following: multiple different systems that are communicating through standards, through government-supported standards that require systems to connect to each other, to be able to share information seamlessly regardless of how the vendor works.

This is how the Internal Revenue Service (IRS) is working with e-filing, since we are coming close to tax filing day. The IRS does not supply software to tax filers. Different companies do, but they all have to meet the IRS filing standard.

This is how banks work with Automated Teller Machine (ATM) software that is used by people around the United States. The Federal Government does not supply that software, but it mandates the standards for how those are used.

This is how cable communications work for our television. They are not supplied by the Federal Communications Commission.

I think we can follow this in health care, and we have made imposing a set of hard-coded, required standards job one. You see that through the certification process, which we have directly linked into the self-referral and anti-kickback safe harbor that we have proposed, that we are linking government policies to the use of those standards. I think this is the way to go that preserves both the best of innovation, the best of our investments to date, and something that does achieve the vision that many of us have for the future.

Chairman JOHNSON. Thank you very much, Dr. Brailer.

Mr. Hulshof?

Mr. HULSHOF. Thank you, Madam Chair.

A great analogy, Dr. Brailer, especially as I have immersed myself in our tax forms trying to reach the deadline, and, again, there are a variety of products out there on the market, but the standards must be a certain level.

Let me, in fact, pick up a word you used about obsolescence and talk specifically about ICD–10. One of the things—and, Dr. Cohn, you referenced the panel that is coming, and one of the advantages of getting to peruse statements and testimony that is likely to come, it is my understanding that ICD–9 is running out of codes in certain categories, at least on the procedural side, and one specific—CMS has started placing things like breakthrough cardiac devices into unregulated procedure categories. So, I wanted to get you with your hat for NCVHS which has in the past gone on record stating that ICD–9 is "increasingly unable to address the needs for accurate data for health care billing, quality assurance, public health reporting, and health services research."

In fact, I think back in 2003, NCVHS also said that moving from ICD–9 to ICD–10 would be "in the best interest of the countries."

First of all, do you still stand by those statements of 2003?

Dr. COHN. Certainly the Committee does.

Mr. HULSHOF. To sort of anticipate some of the criticisms of moving in that regard, do you think ICD–10 will lead to improved billing, quality assurance, public health reporting, health services research? What are the benefits of ICD–10?

Dr. COHN. Well, in preparation for this session, I went back and actually reviewed the November 2003 letter, and I was reminded that this was based on a combination of eight hearings plus we actually commissioned a Rand study to actually look at the costs and benefits, because this was such a contentious issue in the industry. I don't know what your other hearings are going to be like today or have been previously, but I suspect that it will continue that theme.

After much deliberation, I think the Committee came away believing that the costs and benefits were—that the benefits obviously outweighed the costs of moving to a new code set for diagnoses and procedures, in other words, replacing ICD–9 CM, both diagnosis and procedures.

Now, if you look at our letter, I think we also felt that there was really a need to move to a (Notice of Proposed Rulemaking process, among other things to really in a structured way better understand from the industry if there were ways that we could help support the implementation, do it better, minimize costs of implementation, support the transition—all of the things that if you are thinking about a large project you would like to know up front. So, we thought it would be a very valuable thing, and indeed, as we were talking about it this year or at the NCVHS, we decided it was time to ask the department ourselves for a briefing on exactly where they were since, I think as you commented, it has been a couple of years now since that letter was sent to them.

I would, of course, remind everyone that as part of the NCVHS statutory responsibilities under HIPAA, ICD is a HIPAA medical code set, and so it is really our responsibility to—and this is really yet another version change issue in HIPAA. It becomes really our responsibility to look at this and try to provide the Secretary the best advice upon which to base rulemaking.

I don't know if I have answered your question, but at least I have talked some about it.

Mr. HULSHOF. I appreciate that.

Dr. Brailer, in the few moments I have remaining, I want to shift gears a bit and pick up on something in your written testimony. In fact, you alluded to it in your oral testimony about secure messaging. In specific, there is a high-profile incident in Missouri, a former United States Senator, Ms. Carnahan, who had a heart incident, and because of remote monitoring, a very positive outcome. So, I want to touch base just briefly.

I think remote monitoring holds great promise for managing chronic disease, as you reference in your testimony, whether it is congestive heart failure, diabetes, arrhythmia, a host of other potential maladies. So, I think everyone would agree it is a particularly valuable tool.

My question is: Given that Medicare does not often reimburse for remote patient management services, what options do you think are necessary to support and promote the use of technology like remote monitoring?

Dr. BRAILER. It is a really good question, and I think your observation that the transformation of remote monitoring and telemedicine and the ability to actually support health care where the doctor and the patient are not in the same room together is something that will not only change chronic care management, but we see it being a primary tool in prevention, where health care prevention is occurring in someone's home, not when they go to the doctor.

So, it is really a great potential, and we chose the physician-patient communication, the secure messaging, as if—the thin end of the wedge, if you would, to start with something that is quite dis-

crete and quite in demand, because it really is precedent-setting with respect to all of these remote services.

There are a few enablers. Privacy and security is one of them. There really are unusual circumstances raised through remote monitoring because it goes through entities that are not considered in prior laws. So, we have to look at that.

There are standards issues. There are not standards in all of the areas where we want to do remote monitoring. It is a new area that has not been considered. It has been very much, if you would, the standard orthodox concept of a laboratory test or something not remote telemetry or things like that. So, we have some standards issues that we are dealing with. We clearly have the issue of the reimbursement, the cost issue.

Now, with secure messaging, it turns out that clinicians get a substantial benefit because they are taking phone calls anyway. Secure messaging lets them do what we all do with e-mail, which is respond to them all at the end of the day.

I think as we go out into these questions of telemedicine, e-ICUs, remote ambulatory chronic monitoring, there is not a very good concept of this cross-site model. So, what we are going to do with this is begin exploring and looking at demonstration projects that can understand what the configuration is that is necessary. Who does the information go to? What is their responsibility to act? Within what time? How does that relate to traditional primary care?

Those demonstrations will help us sort out that configuration, which will have economic implications that we would like to bring forward. So, we are going to start with this piece and make it work, and then carry it out through a number of other areas.

Chairman JOHNSON. Mr. Emanuel?

Mr. EMANUEL. Thanks, Madam Chair.

Dr. Brailer, I was going to ask about privacy, but in your answer to a follow-up question that the Chair had asked to Congressman Stark's question all about the national standard, you cited other areas, both banking, financing, cable, telecom, as good examples for where those should be kind of road maps going forward. I think broadband you also mentioned, but in each of those areas, the United States is behind other countries both in use and technology development.

Now, originally, I actually leaned toward setting some kind of boundaries from the National Government standard and then letting the private sector develop the technology and use that investment eventually then to kick in where we really kind of have one national system.

I do worry, where Congressman Stark is, that without stronger national standards, we will end up with a series of different silos and what you won't get is the benefit of a single national standard, which has its problems and drawbacks. In every area where we set some standards and then let each of the private sector companies, individual companies develop a program, I just—you used the analogy. I didn't. I happen to think medical records and information are slightly different than your ATM machine, but we will use that analogy. It is your analogy, but in broadband, cable, ATM, financial records, in every place, both U.S. citizens' use of that information

and capacity to use that information and do more things with that information is way behind all our competitors. Since that is your analogy and, therefore, it is your mind-set. My instinct is to lean where you are, but I will tell you, you look at broadband, we are behind almost all our economic competitors and falling behind because of an approach that has not been a universal standard.

You look at financial information, which we should have been the leader of in using electronic transfer of information, we actually have fallen behind our major competitors in Europe. Then telephones, I think that information is well available and out in the public domain.

So, my concern with that analogy and that mind-set and, therefore, that practice is in every one of those examples we do not lead. We are way down in the pack, and not even near close to the top.

So, between, as you try to find—and I really—when we first discussed this in private as just a Subcommittee, without any hearings, and we were in the room across the hall, my instinct is to lean toward setting some standards and then let each of the companies and each of the ones kind of get the best practices out there, but what happens when you set that in play is exactly where we are in telecom, exactly where we are in broadband, exactly where we are in financial services—and you used cable—also cable. We are behind every major industrialized country.

So, if that is what we are going to do, let's just do it eyes opening that we decided to finish close to the back of the pack. We are looking the only place in the medical field where you can find—whether it is 150, 300 billion dollars of free money with a little investment. The bang for the buck is like nowhere else, outside of maybe preventative care.

I did not mean to kind of rant, but it is 3 o'clock and I got nothing else to do for the rest of the day, so there goes. I would be interested in you spending a little more time on this because this is the—we can deal with privacy. We will figure that out hopefully. This, though, is the crux of whether we walk literally by $300 billion—maybe $150 billion. Somewhere in that zone. Nobody really knows. It is a guess.

This is the issue, and in every one of your analogies, we are back in the bottom of the pack, where we used to be in the front because we followed that approach.

I would say one last thing. I kind of leaned where you were. I was firmly on the other side. Save me.

Dr. BRAILER. I am going to encourage you to keep leaning. The question of standards is one of a trade-off, and the finesse of this trade-off is something that is really at the heart of your question. It is the degree to which homogeneity is enforced, with strict, exacting measure versus the degree of innovation and experimentation and evolution that is born in these.

The U.S. health care industry is at the extreme side of innovation. That is why we have 32 standards organizations that have conflicting and overlapping standards, and the disarray we have in our standards fabric in the United States for health information is quite large. We have inherited this problem. It has been originating in the past, and I cannot comment on how we got here, but we certainly want to move it toward an area that is quite more homo-

geneous. However, the question is: Do we go all the way to the extreme to a heavy-hand imposition to say this is it? Because we know that the ossification and the sclerosis that comes around that can cause us problems in 5 or 8 years.

So, I cannot tell you the exact tonality, but I do understand the trade-off that is being made here.

Mr. EMANUEL. Madam Chair, could I—I would only ask for 1 minute. Okay?

Chairman JOHNSON. Go ahead.

Mr. EMANUEL. The trade-off is, if you say we have got a big foot and here is the deal, because then you have a system, given technology, within 10 years that is obsolete, as you would say, or behind the curve. In that same timeframe, without setting some real standards and guidelines, 10 years hence we are going to have so many competing demands, all the efficiencies that you could have gotten, i.e., the $150 to $300 billion, is lost. I would say this: You said a template and a foundation of technology, and we have seen it today with the announcement by—just take Apple, for example, their announcement. You set the foundation down from a technological standpoint. You can always upgrade that system. You have massive differences out there. The integration capacity is never going to be financially cost-effective, and that is my worry. You can improve 10 years hence with a, quote-unquote, homogeneous, big-foot system. You cannot do that once you have so many competing systems that you never, ever achieve the economic efficiency of $300 billion in savings, 150, whatever the dollar is.

Chairman JOHNSON. Let me just make——

Mr. EMANUEL. That is the trade-off here.

Chairman JOHNSON. Let me make a comment on this exchange, because I would ask you both to direct your attention in the coming couple of weeks during break to the last section of the bill where we ask the AHIC to report, because we are trying to in that report force some discussion of what is the entity that follows your office, Dr. Brailer. Even if we keep the office there, what is the nature of the public-private partnership that continues to oversee these standards and make sure that we get the ability for a standards change management process that is more appropriate and timely than we have in other sections of the law?

The reason, at least in my view from being here a long time, the reason you were able to describe the situations you describe—and you are absolutely right—is because we down here, we make a law, then we forget it for 5 years. Then we may or may not do something for another 5 years, but we do not have a process built into anything that is organic and fast and timely and responsive to private sector needs.

Dr. Gingrey has joined us to listen to the testimony because he has in his district some very smart, very small proprietary start-ups who have done wonderful boutique things. While we want them to have their doctors be interoperable with everyone else, we do not want to squelch their ingenuity because their ingenuity may be the next generation of national need.

So, I think we are talking about the same thing, but what is important about this bill, in my mind, is not that it establishes the office. We have to take on the challenge that Dr. Cohn pointed to

of some kind of process that allows continuous upgrading management, with consensus and public input, but is different than the heavily regulatory, very time-consuming processes by which we have generally operated. I think when Dr. Brailer's people come back from the States and say what are the situations here, we are going to get a pretty stark view—with all due respect—of the strengths and weaknesses of our privacy laws and their ability or inability to allow us to move with the times.

So, you hit on a very key thing. Thank you for enlarging on it, and there are a couple of places in the bill where we are trying to look to the future. We may want to be more specific, enlarge that language, but in Dr. Brailer's testimony, the panel that helped to get you started, they repeatedly talk about the absolute necessity of—you say it here—unanimously agreed that the Federal Government must begin to drive change before the private sector will become fully engaged. The leadership panel identified a key imperative that the Federal Government should act as leader, catalyst, and convener. We have to maintain that interest and position of the Federal Government, but if we start mandating technology, then we will make everything obsolete in a very short period of time.

So, we will come back to this issue, keep thinking about it, and as you look at the bill, we welcome your input.

Mr. Thompson of California?

Mr. THOMPSON. Thank you, Madam Chair.

Dr. Brailer, some of the—I am sure not just in my district, and throughout the country, there are some places that are moving in the IT direction already and have made in some instances some pretty substantial investments in this area. They are very proactive, getting from that proverbial curve.

What are we doing to make sure that they are not penalized for their early investment and the early work that we are doing?

Dr. BRAILER. It is a very good question, and you do represent a district that has had some substantial innovation and leadership, put a substantial effort into that that we are now looking at to understand what the lessons are for the rest of the United States

I think it is an art because we cannot guarantee those systems that we will preserve their investments intact such that we will—for example, when we do adopt standards, that we will not require them to change a system or change part of their investment. On the other hand, we certainly do not want to be derelict and create a wholesale switchover of what could be a very large and worthwhile investment.

So, I think the two key principles that we are following are develop broad consensus so that people who are early leaders and followers, people from all stakes are able to represent their participation in this. Ultimately, standards are questions of economic determination, not technical determination in terms of winners and losers, and we want to make sure that all people are consulted; and, secondly, have sufficient lead time. This is one of the reasons that we have not pursued this as a mandate, to make sure that a system in your district or elsewhere who did have to make a change would have years or a period of time to make the change so that

they could do it incrementally, package it in, if you would, with the next upgrade of their equipment that they already have.

Even if today we mandated the industry to have standards, the level of investment that has already been made would take years, up to a decade, for it to be switched out and to be put into these new technologies. So, I think it is incremental and it is guided by these standard-setting processes.

Mr. THOMPSON. So, there is going to be ongoing consideration of this and some sort of—"hold harmless" is the right terminology, but an understanding of whatever comes along takes into consideration this early innovation.

Dr. BRAILER. It is. Again, the core issue here, sir, is if the standardization of our health information was a one-time event, if we are able to say here it is and it is done and it is fixed, it would be really easy to deal with these questions. We could have much more degrees of freedom with systems or investments, but it is a process. It is never-ending. As soon as we think we are done, new information, new innovation, genetic data, remote monitoring data—whatever it might be—is innovated, and that creates new requirements.

So, it is a process, and what we are trying to do is to get doctors and hospitals in the process so their investments are standardized. The key thing we are doing right now for ambulatory information is ambulatory electronic health records that don't meet the certification requirement will not gain access to Federal policies that we are putting forward. That begins pushing people in that direction in a gentle way, and it gives them a guideline. We are going to do that for the inpatient setting and for other things as we go down the road.

Mr. THOMPSON. Because all doctors and all hospitals don't come in the same shapes and sizes, and especially in an area such as the one that I represent, there are a lot of rural areas, and more often than not rural folks are solo practitioners, and they are in a little different spot as far as being able to capitalize some of these new innovations. Is there going to be any type of—do you see any way to provide help for these folks?

Dr. BRAILER. Well, yes, it is a great question, and we do face an adoption gap in the United States in that we have very large systems, like Kaiser and big physician groups, some in your district, who are way ahead, years ahead. Then we have many doctors—30 percent of doctors in practice are not able to gain access to this. Our efforts are aimed at three tasks: first, lowering the cost of these technologies, making sure that as doctors in small practices——

Mr. THOMPSON. Even if you are able to lower them, though, it is a bigger burden on solo practitioners in rural areas than it is——

Dr. BRAILER. I agree. I spent time yesterday in Texas with a lot of solo practitioners dealing with this very question. We want to take those who are willing and make sure that they can come along, lowering the cost, raising the economic value through pay for performance and other incentives, and lowering the risk. One of the issues that many doctors tell us is that they could probably understand how to do this financially, but it is so risky, it is such a big thing for them to do, and certification and other things we are

doing are risk-lowerers. They help them take out the uncertainty of what the product is supposed to do.

So, we are trying to look at this in terms of how they make a business decision, but ultimately, I am sure that there are going to be clinicians, safety net clinics, and others that cannot come along, and that is going to be a cause for action to really understand how do we make sure that this is a level playingfield. I don't think the time is now, but I do think there will come a time when we have to make sure that everyone is able to do this.

Mr. THOMPSON. Thanks, Madam Chair.

Chairman JOHNSON. That point that you raise, Mr. Thompson, is an extremely important one. It is not just that small practices of one, two, three, and four physicians, where most of our physicians are practicing, are going to have a hard time. However, in rural areas, there is going to be a particularly difficult time, and that is why—and I was discussing this earlier with Mr. Morris. That is why some of us advocate the exception to both the civil monetary penalties law and the Stark law, because I want to try to let—in the proposed safe harbor is just hospitals and a very limited number of people. If there is a big employer, if there is a hospital, if there is an insurer that covers people in that area, they have deeper pockets, and they ought to be able to continue, and they ought to be able to provide a very deep discount or for free to some of these practitioners. Equally important in the rural areas is going to be support for this technology, and we cannot have these little offices trying to trouble-shoot these systems that are really way beyond—we in the House as Members do not try to do that, and we cannot put them out.

So, one of the reasons I want sort of any group who wants to participate in contributing to the cost of this technology to get in there to do that because there are systems winners in this, the first year. Everybody is a winner across the board, but it is going to so dramatically improve reporting and reduce costs for some groups, like insurers and hospitals, earlier than for others, but I want them to get into paying.

So, that issue that you raise is a very serious one, and while it does not show that it is addressed in this bill, and while we need to talk about whether that is necessary to address it, I personally firmly believe it is necessary.

I thank the panel for their patience. I thank the Members for letting the panel go beyond in their time to get at the questions that have been asked, because they have bee very good questions.

I would ask you, Dr. Brailer, that as you look at the cross-site model and what we are going to do about that, you also look at this new model that the American College of Surgeons has developed called the "Medical Home," because we are not suited to reimburse for that either, and yet technology is going to make that possible, and making that possible will let these rural family doctors get a level of reimbursement that, frankly, if we do not give to them, they will not survive. Also, if we do not let them have a larger mental role in health care, they will not want to be there.

Mr. STARK. May I have one short——

Chairman JOHNSON. You certainly may.

Mr. STARK. Dr. Brailer, what would be your position on requiring that whatever system we use be an open-source system?

Dr. BRAILER. We have weighed in very solidly, sir, to say that of the standards that are used for these systems, that determine how information is going in, comes out, or is stored, are in the public domain and are non-proprietary, non-royalties bearing.

Mr. STARK. So, it should be open-source.

Dr. BRAILER. Well, open-source goes beyond that. That is a software development methodology that we think is one alternative the market could pursue as a way of generating the solution. You have witnesses in the next panel who will tell you about that, and it is a very promising approach. To us, the key leverage point is to have public domain standards so that no one controls what the methodologies of data access or data writing or data using are. If the market moves toward open-source because it is a better model, more innovative, more cost-effective, so be it. If it leads to proprietary software, our view is, provided that it uses the standards and information is portable and cannot be sequestered or treated as a proprietary tool, we support it.

Mr. STARK. Thank you.

Chairman JOHNSON. Thank you very much. I thank the panel and I invite the next panel forward. While the second panel is assembling, I will announce that we will leave the record open for questions, as there are some who have indicated that they have questions and could not either get here in some cases on time and in other cases at all.

We are welcoming Brent Henry, the Vice President and General Counsel of Partners HealthCare, Boston; Dr. Kenneth Kizer, the President and Chief Executive Officer of Medsphere; Joseph Smith, the Senior Vice President and Chief Information Officer of Arkansas Blue Cross/Blue Shield; and Gloryanne Bryant, the Corporate Director of Catholic Healthcare West.

I have read your testimony, and I am really pleased to have you here to contribute to our discussion of this issue and to help us refine and strengthen our approach. With that, I will recognize Mr. Henry.

STATEMENT OF BRENT L. HENRY, VICE PRESIDENT AND GENERAL COUNSEL, PARTNERS HEALTHCARE SYSTEM, INC.

Mr. HENRY. Thank you very much, Madam Chairwoman. My name is Brent Henry. I am Vice President and General Counsel for Partners HealthCare in Boston. Thank you for the opportunity to testify today. I am going to be speaking to the fraud and abuse barriers to the adoption of health IT, which I will refer to as health IT, in light of the limited time we have.

Our work on this issue in Washington began well over a year ago, with meetings with HHS when we sought a CMS advisory opinion and were told to wait for regulations. We have been waiting for quite some time.

We recognize that our situation is somewhat unique because we are leader in this area, but since we are a leader in this area and since we were told to wait for regulations, which have not been forthcoming yet and we have not been able to obtain an advisory opinion under the Stark laws, we are here supporting a legislative

change which will give us some opportunity, we hope, to lead the way.

Partners HealthCare is one of the largest diversified health care services organizations in New England. It was founded in 1994 by Brigham and Women's Hospital and Massachusetts General Hospital, and now includes three community hospitals, a psychiatric hospital, two rehabilitation hospitals, and a physician network of approximately 5,900 primary care physicians and specialists, about half of whom are employed.

We are committed to the vision of a health system that utilizes the promise of health IT to the fullest extent and have made significant investments in this area. We applaud Representative Johnson for introducing H.R. 4157, which would help remove some of the current regulatory barriers to the more widespread adoption of health IT.

Partners' strategy is centered around five signature initiatives: one, maximizing the use of clinical IT; two, increasing patient safety and reducing medical errors; three, making high-quality patient care uniform across our system; four, coordinating care for patients with high-cost diseases; and, five, improving the efficient use of prescription drugs and radiology procedures.

In pursuing these initiatives, the implementation of a system-wide EHR program is key. We have data that show doctors who use EHR score higher on both efficiency as well as quality measurement scales than those who do not. In Massachusetts, the payors have recognized this and have negotiated pay-for-performance contracts with providers that incentivizes us to achieve certain efficiency and quality targets that can only be reached through the use of EHR and other related health IT. Our challenge at Partners is that while 80 percent of our employed physicians have access to EHR, fewer than 20 percent of our community-based physicians are using that technology. The reason is simple: Cost.

To accomplish its goal of a network-wide EHR system, Partners needs to provide non-monetary support to its community physicians to assist them in deploying EHR technology. However, the fraud and abuse laws impose significant barriers on our ability to do that. Under the Stark law, such support would constitute a "financial relationship" with physicians who might possibly refer to us and would, therefore, subject us to significant civil monetary penalties and risk of being excluded from the Medicare and Medicaid programs. The anti-kickback statute contains criminal penalties, and there are few hospitals that are willing to take the risk of violating that statute by providing technology to physicians that could be considered to be "remuneration" without some official guidance or safe harbor suggesting these types of activities are allowed.

We believe in strong enforcement of the fraud and abuse laws. They were enacted to combat the corrupting influence of money on physicians' decisions to refer patients and order services. However, these laws are having an inadvertent chilling effect on the widespread adoption of health IT.

That is why we support the efforts like those in the Johnson bill to craft an exception and an anti-kickback safe harbor for the provision of health IT to health professionals while maintaining the

basic framework of the current laws by stipulating that such support is not tied to referral considerations.

We applaud CMS and OIG for their initiatives in issuing proposed rules last fall in this area. However, there remain significant questions as to the ultimate timing and impact of these proposals, and we believe that legislation may still be necessary. The current CMS and OIG proposals offer limited prospects for meaningful relief, and I have submitted our concerns about them in detail in my written remarks. I will not have time to go into them now, but would be happy to answer questions with respect to our suggestions there. We believe that these proposals reflect a deeply skeptical view of providers' reasons for donating technology. Consequently, we ask Congress to act clearly to show that fraud and abuse protections can be harmonized with the public policy of strong support for the widespread adoption of health IT.

Research has shown that having the right information available in the right place at the right time can dramatically reduce medical errors. It can improve quality, and it can improve efficiency in the delivery of health care. To maximize the value that increased use of health IT can bring to the health care system, it is necessary to encourage adoption by physicians, not just hospitals. One way Congress can facilitate greater physician adoption of EHR is to allow hospital systems like ours that have successfully implemented these systems to share their expertise and health IT investment with community-based physicians.

I thank you for the opportunity to testify today and would be happy to answer any questions with respect to my written testimony.

[The prepared statement of Mr. Henry follows:]

Statement of Brent Henry, Vice President and General Counsel, Partners HealthCare System, Boston,

MA Good afternoon. I am Brent Henry, Vice President and General Counsel for Partners HealthCare in Boston. Thank you for the opportunity to testify today on issues regarding health information technology. My remarks are focused on regulatory barriers to the adoption of health information technology (HIT), specifically the physician self-referral (Stark) and anti-kickback laws and how Congress can spur significant progress in this area through the enactment of limited relief under these laws.

Partners HealthCare is one of the largest diversified health care services organizations in New England. It was founded in 1994 by Brigham and Women's Hospital and Massachusetts General Hospital in order to create an integrated delivery system. In addition to the founding academic medical centers, the Partners system now includes three community acute care hospitals, one hospital providing inpatient and outpatient mental health services, three hospitals providing inpatient and outpatient services in rehabilitation medicine and a physician network of approximately 5,900 primary care physicians and specialists, about half of whom are employed.

The dramatic positive benefits of increased efficiency, cost savings, and quality that can be derived from the use of cutting edge health information technology are well-documented. Partners is committed to the vision of a health system that utilizes the promise of that technology to the fullest extent and has made significant investments in this area. We applaud Rep. Johnson for introducing H.R. 4157, "The Health Information Technology Promotion Act", which we believe would help remove current barriers to the more widespread adoption of health information technology.

This technology is one of the building blocks of our efforts to become a truly integrated health care delivery system that improves the quality, safety and efficiency of care for its patients. Partners' strategy is based around five Signature Initiatives:

1) maximizing the use of new clinical information technology;

2) increasing patient safety and reducing medical errors;

3) making high quality patient care uniform across the Partners system;

4) coordinating care for patients with high cost diseases; and

5) improving the efficient use of prescription drugs and radiology procedures.

In pursuing these initiatives, the implementation of a system-wide electronic health records (EHR) program is key. It is the EHR that provides the data and the communications capabilities to make the other Signature Initiatives possible. To date, programs instituted under the Signature Initiatives have improved the quality of care for the sickest patients by meeting or exceeding national standards for the treatment of heart disease and diabetes; have reduced hospital re-admissions among patients with congestive heart failure by 20 percent and have improved coordination of care for these high-cost patients; and have reduced the rate of increase in out-patient drug costs. We have data that show doctors who use EHR score higher on both efficiency and quality measurement scales than those who don't. In Massachu-setts, the payors have begun to recognize this and have negotiated "pay for perform-ance" contracts with providers that incentivize us to achieve certain efficiency and quality targets that can only be achieved through the use of EHR and other related information technology. The challenge we face is that today, while close to 85% of our employed physicians have access to EHR, fewer than 20%of our community-based physicians are using that technology. The problem is simple. Cost.

To accomplish its goal of a network-wide EHR system, Partners needs to provide non-monetary support to its community physicians to assist them in deploying EHR technology. However, the fraud and abuse laws impose significant legal barriers to our ability to support the non-employed physicians in this way. Under the Stark law, such support would constitute a "financial relationship" with physicians who might possibly refer to us, and would therefore subject us to significant civil mone-tary penalties and risk of being excluded from participation in the Medicare and Medicaid programs. The anti-kickback statute contains criminal penalties, and no provider is willing to risk violating that statute by providing technology to physi-cians that could be considered "remuneration" without some official guidance or safe harbor suggesting these types of activities might be permissible.

We believe in strong enforcement of the fraud and abuse laws. These laws were enacted to combat the corrupting influence of money on physicians' decisions to refer patients or order services. However, these laws are having an inadvertent chilling effect on the widespread adoption of health information technology that could have a dramatic positive impact on health care delivery.

For this reason, we support efforts such as those included in the Johnson bill to craft a Stark law exception and an anti-kickback safe harbor for the provision of health information technology and related services to health professionals. Under the bill, non-monetary support for HIT would be allowed if: (1) there is no restric-tion on the use of HIT to services from the entity providing the technology; (2) there is no restriction on the use of the donated HIT in conjunction with other HIT; and (3) the support provided does not take into account the volume or value of referrals.

These provisions will allow systems like Partners to move forward with invest-ments in information technology by providing a clear roadmap for permissible as-sistance that can be provided in terms of hardware, software and related training, maintenance, and support services to physicians who cannot afford to make those investments on their own. At the same time, it would maintain the basic framework of the current laws by stipulating that the provision be clearly limited to support that is not tied to referral considerations.

We strongly believe that the benefits derived from the increased adoption of HIT are enormous and can be achieved in a manner that does not create inappropriate incentives for physicians, their referral patterns, or clinical practices. Partners is committed to the goal of delivering high quality medical care in community settings, and therefore its care delivery model is based on maintaining the relationships that its community-based network physicians have with their community hospitals. Therefore, in providing support for the adoption of EHR technology it is integral to Partners that we do nothing that would negatively impact those relationships. Part-ners estimates that approximately 60 percent of the community network physicians targeted for EHR support, have primary affiliation relationships with non-Partners hospitals (71 percent for primary care physicians). Because so many of these physi-cians have primary affiliations with other hospitals, they will not accept an EHR system unless we can guarantee that it will be interoperable with those other hos-pitals' systems when they come on line.

Some have asked why legislation is necessary given that the Department of Health and Human Services (HHS) has the authority to promulgate regulatory pro-tections. Recently, the Center for Medicare and Medicaid Services (CMS) and the

HHS Office of the Inspector General published proposed rules to create safe harbors under the Stark and anti-kickback statutes to remove barriers to the adoption of e-prescribing technology and electronic health records. We applaud these initiatives. However, there remain significant questions as to the ultimate timing and impact of these proposals, and we believe that legislation in this area is still necessary. The current CMS and OIG proposals offer limited prospects for meaningful relief for the following reasons:

- The OIG did not propose a safe harbor but only solicited comments on whether one should be considered. Thus, the likelihood of comprehensive final regulations in the near term is very low.
- Hospitals are listed as proposed HIT donors, but that list does not include systems that own or manage multiple hospitals, nor does the list include management support organizations and physician hospital organizations. All of these types of entities need to be listed as permissible donors to attract appropriate adoption and development of HIT.
- Similarly, the list of potential recipients is limited to "hospital staff", a designation that excludes non-medical staff physicians who are part of a health system's network and others who care for patients over a wider geography. This narrow listing of permissible recipients severely undermines the utility of the rules and thwarts Partners efforts as discussed earlier in my testimony.
- The covered technology under CMS's proposed exceptions is too restrictive to be of much practical value. The proposal only protects software and directly related training and excludes software interfaces, upgrades and ongoing technical maintenance and support for software (such as "help desk" support), which are integrally related to an effective HIT program and therefore critical to include in meaningful exceptions.
- The CMS regulations contain both "pre-interoperability" and "post-interoperability" exceptions. We support the approach taken in HR 4157 to require the EHR technology to meet standards once they have been promulgated and adopted by the Secretary, and to provide a transition period so that providers can bring their systems into conformance with the new standards.

While HHS can certainly make changes in its final rules, we believe the current proposals reflect a deeply skeptical view of providers' reasons for donating technology. Consequently we ask Congress to act to clearly show that fraud and abuse protections can be harmonized with a public policy of strong support for the widespread adoption of HIT. Because of uncertainty surrounding the proposed rules and the limited degree of protection they afford, hospitals and physicians are taking a wait-and-see approach in the hopes the future will bring a better deal. As a result, important progress providers have made in adopting IT technology will stagnate.

Summary

Research has shown that having the right information available in the right place at the right time can dramatically reduce medical errors, improve quality, and improve efficiency in care delivery. To maximize the value that increased use of IT can bring to the health care system, it is necessary to encourage adoption by physicians, not just hospitals. One way Congress can facilitate greater physician adoption of EHR is to allow hospitals and medical groups that have successfully implemented these systems to share their expertise and IT investment with community-based physicians.

We believe the enactment of fraud and abuse protections, consistent with the underlying policies of those laws, will encourage adoption of EHR and provide immediate benefits to consumers in the form of higher quality and lower cost.

I thank you for the opportunity to testify today and look forward to working with you and your staff on this issue.

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Chairman JOHNSON. Thank you very much, Mr. Henry.
Dr. Kizer?

STATEMENT OF KENNETH W. KIZER, M.D., CHAIRMAN AND CHIEF EXECUTIVE OFFICER, MEDSPHERE SYSTEMS COR-PORATION, ALISO VIEJO, CALIFORNIA

Dr. KIZER. Thank you and good afternoon, Mrs. Johnson, Mr. Stark, Members of the Committee. Thank you for asking me to appear before you again.

I know how much you have heard about these issues. I do not think I need to make the case about why we need electronic health records and a national health information infrastructure, so let me go directly to three suggestions for ways that the Congress might accelerate the adoption of electronic health records and do so at a cost substantially less than what has generally been talked about in the past.

For the past 20 years, open-source software has been building momentum. Open-source now has established its viability in the commercial world, and there is a major shift going on around the world toward open-source software as being the preferred solution. While open-source software is less well developed in health care than for some other enterprises, a number of open-source solutions have appeared on the market for health care in recent years, and this is probably the most rapidly evolving area of open-source software.

I would urge the Committee to consider making open-source software the first consideration in selecting software purchased with Federal funds, whether that be through the Federal agencies or through Federal funds that are used by the States or by individuals, including research funds.

In my written testimony, I have gone through a number of the advantages of open-source software. Indeed, in this scenario, open-source software is viewed as a commodity. We give away the Code for free. Companies compete on the basis of how well they actually serve their customers based on that free software. I would encourage Congress to do the same as a number of States and other countries have done and legislate that open-source software must be first considered when Federal funds are used to purchase new software. If there is not an appropriate open-source solution, then one could purchase the proprietary software.

I was interested in Mr. Emanuel's comments and questions when he talked about how the United States compares to other countries in a number of areas, and I can tell you that much of the rest of the world is moving as fast as they can toward open-source software because of its many advantages.

The second point I would like to make is that in promoting development of a national health care information infrastructure and widespread adoption of electronic health records, we do not need to start at ground zero. I would urge the Committee to consider how it might capitalize on the sizable public investment that the government has already made in VistA, the electronic health record used by the Department of Veterans Affairs and increasingly by the Indian Health Service. A variant of VistA is also used in Department of Defense facilities.

I am not going to take the time here to go into the history of the VA's development of this product. I would certainly acknowledge, as the person who implemented VistA in VA in the later part of

the nineties, that it is not a perfect system. It has its flaws and limitations, however, it is markedly better than what most hospitals have in place today.

It is unfortunate that this very successful product developed by the government with taxpayer dollars cannot be made more available to benefit community, rural, and public hospitals. It is also unfortunate that improvements in VistA that have been made in the private sector in the last couple of years cannot be fed back into the VA to benefit the government in its use of this product.

To address these two issues, I would urge the Committee to consider redirecting a portion—5 percent perhaps—of the funds that are annually appropriated to the VA for research and development of VistA, and specifically those development funds, for a 5-year period to create a public-private partnership whose purpose would be to promote the use of VistA by supporting open-source development of the VistA code, bi-directional sharing of enhancements, the development of interfaces with proprietary systems (especially the legacy back office systems that most hospitals want to keep in service) standards of interoperability where those might be needed, and validation of those improvements so that this public domain product can benefit both the government and private health care providers.

I would expect that at the end of 5 years, the partnership would be self-sufficient, and so would no longer need these funds. By that time, also, the VA itself should be realizing substantial benefits from the enhancements in the system that have been fed back to it. The investment should more than pay for itself in the short term.

I should acknowledge that in my written testimony, I refer to this Committee as authorizing this budgetary change, but I am aware that there is a separate VA Appropriations Committee and that these are issues that would need to be dealt with by the relevant VA Committees. In that vein, I have made copies of my testimony and comments available to the relevant VA Committees.

The third recommendation I would posit for your consideration— and in doing this I should state for the record that I did not know, Mr. Stark, of your position in this regard, but I would urge the Congress to set a date certain after which use of an electronic health record would be a condition of participation in the Medicare Program, and anyone who wishes to participate in Medicare would have to use an EHR. I also recognize, having run a large health care system, that you do not do these things overnight. There is a need for some advance lead time. So, if we were to pick a date— say 2015, just for purposes of discussion—I would also encourage the corollary consideration that at some time before 2015 the Congress also consider setting a differential reimbursement rate under Medicare for those facilities that use an EHR. They would receive one rate, and those who did not would receive a lesser rate. As we saw a couple of years ago in the reporting of quality metrics, when Congress said that reporting would be associated with getting the annual Medicare adjustment, there was a marked change in hospital reporting in a matter of weeks.

I think that if the Congress were to do that, it would also need to specify certain elements of what would qualify as an electronic

health record. I can see from the clock that I have exhausted my time, so I will not take the time to further detail the things that are included in my written testimony as examples of the elements that would need to be included to qualify under this provision as an electronic health record.

With that, I will stop and I will be happy to address your questions at the appropriate time.

[The prepared statement of Dr. Kizer follows:]

Statement of Kenneth W. Kizer, M.D., President and Chief Executive Officer, Medsphere Systems Corporation, Aliso Viejo, CA

Good afternoon. I am pleased to appear before you today to comment on how Congress might accelerate development of a national health care information infrastructure and speed up adoption of electronic health records and to do so at a substantially lower cost than generally thought to be necessary.

At the outset, I should acknowledge that I am cognizant of the large amount of testimony that this Committee has heard over the past two years about health care information technology and ways to improve the quality and safety of health care. I know that I have contributed testimony on at least two previous occasions (March 15, 2005 and June 17, 2004). Being mindful of this, my background comments are intentionally very brief.

Background

In the way of background, I would again note that few technological advances have held so much potential to improve health care, yet has so far realized so little actual impact on everyday patient care, as has electronic information management. This is especially ironic when one considers that modern health care is the most information-intense enterprise that human beings have ever engaged in and that many of health care's diagnostic and treatment technologies are models of electronic sophistication. Unfortunately, the methods of maintaining and moving patient-related information along the continuum of care have remained much the same for the past 100 years.

The absence of a national health care information infrastructure to support coordinated, continuous and comprehensive, patient-centered health care contributes to an unacceptably high rate of medical errors; hinders efforts to measure health care performance and improve known deficiencies of quality; and impedes improvements in efficiency.

I believe that the single most important thing that can be done today to improve the quality and safety of health care and to reduce soaring health care costs is to widely adopt electronic health records.

An electronic health record (EHR) should be viewed for hospitals, clinics and other health care organizations the way that enterprise resource planning (ERP) systems are used in other industries. In brief, the electronic health record is a mission critical enabler of consistent and predictable high performance.

Unfortunately, the high cost of most of the electronic health records on the market today make them unaffordable for a large majority of hospitals and other health care providers.

Being mindful of your deep immersion in these issues, I will forego any further comments on why a national health care information infrastructure is needed and what are the benefits of widespread adoption of electronic health records. I know that you are familiar with the reasons why we need to proceed towards these goals with a sense of urgency.

I would like to focus the remainder of my comments on three interrelated but stand-alone recommendations for how Congress could accelerate adoption of electronic health records at a cost substantially less than usually cited in this regard.

Make Selection of Open Source Software the Default Mode for Federal Funds

For the past twenty years open source software has been building momentum in the technical cultures that built the Internet and the World Wide Web. Open source has now established its viability in the commercial sector, and a major shift toward open source software is underway throughout the world.

Open source software is less well developed in health care than for some other enterprises, but open source software solutions for health care are now rapidly evolving.

In this vein, I urge the Committee to consider making open source software the first consideration in selecting any new software purchased with federal funds. This

should be the case across the federal government—for health care and non-health care federal procurement alike. This requirement should apply to software purchases made by all federal agencies and purchases made by state and local governments and private parties using federal funds (including research funds).

Even in the absence of federal funding per se, I believe that the federal government's policy should be to support and utilize open source software as the preferred option whenever possible because of its many advantages over proprietary software.

When using the term *open source software* I refer to software that is nonproprietary, available at no or minimal cost, allows different IT systems to operate compatibly, and facilitates collaboration in order to improve and enhance the freely accessible source code.

Open source software had its genesis in the 1970s with the creation of Berkeley Software Distribution, which sought an alternative to AT&T's Unix operating system. In the 1980s and 1990s the key network protocols underlying the Internet were developed using open source methods.[1] A particularly critical milestone in the history of open source was the creation of the Linux operating system in the 1990s. Linux demonstrated that open source development methodologies could deliver commercially viable technology to the market.

In recent years, a number of non-health care companies (e.g., Red Hat, MySQL, and JBoss) have demonstrated that open source is not only commercially viable but may well become the dominant model for creating software. This likelihood is enhanced by the support shown for open source by leading technology companies such as IBM, Hewlett Packard, Dell, Sun Microsystems and Intel.

Open source software differs from proprietary software in several ways. For example, while competition and the free market are very much a part of open source, the competition occurs at increasingly higher levels of value add. Businesses in the open source arena do not derive revenue from licensing fees, as is the case with proprietary software, but instead generate revenue from ancillary products and services that are tailored to the needs of the individual customer. Companies compete, and differentiate themselves, on the quality of their value add, whether that be in service delivery, product enhancements or other ways important to the customer, and not on the proprietary value of the software itself.

In open source, the basic software is viewed as a commodity and its development is collaborative and shared by the community of users. Because contributions to enhancing the code come from many sources in an environment of collaboration, innovation is more rapid. Likewise, because of the large number of ready testers, evaluation and debugging of new developments is more rapid than with conventional software. Finally, open source gives users of the software much more flexibility because they can obtain software and services from many sources, not just one vendor. Indeed, open source is much more consistent with a true free market approach than proprietary products that entail the infamous "vendor lock."

The health care industry is just now being introduced to this wave of open source innovation, with several new corporate entrants over the last year promising competitive EHS functionality at significant cost savings.

I recommend Congress do as some states and other countries have done and legislate that open source software must be first considered when federal funds are used to purchase new software. If there is no appropriate open source solution available, then one could turn to proprietary options.

I am confidant that the federal government would save billions of dollars in licensing fees alone over the next 10 years by preferentially pursuing open source solutions. The government would likely also realize substantial savings through collaborative public-private projects and increased software functionality while harnessing a robust stream of innovation in the future.

Leverage the Federal Government's Existing Investment in Health Care IT

In promoting the development of a national health care information infrastructure, we need not start at ground zero. The Congress should recognize that it has already invested billions of dollars in developing an electronic health record that currently operates the largest health care system in the nation.

I urge the Committee to consider how it might capitalize on the sizeable public investment that already has been made in VistA, the electronic health record used by the Department of Veterans Affairs and increasingly also by the Indian Health Service. A variant of VistA is also used by Department of Defense health care facilities.

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[1] Forrester Research. *Open Source Software: A Primer for Health Care Leaders*. California Healthcare Foundation. Oakland, California. 2006.

The Veterans Health Administration began developing an EHR in the early 1980s when few clinical options were commercially available. Over the ensuing years, several billion dollars of federal funds were spent developing the VA's electronic health record, which was named VistA in 1996.

Today, VistA is the most widely used electronic health record in the world, as judged by the number of facilities and health care providers using it on a daily basis. It is also the most successful electronic health record in so far as its use has been linked to dramatic improvements in the quality and safety of care, as documented in numerous peer-reviewed articles and other reports in the medical literature.

In the past two years, VistA has been successfully deployed in both the private sector and in health care facilities run by state governments.

As the person who implemented VistA in the VA in the 1990s, I will certainly concede that VistA is not perfect and would benefit from improvement in some areas, just as would all of the proprietary systems currently available. However, even with its limitations, VistA is markedly better than what exists in most hospitals today.

It is unfortunate that this successful product developed by the government with taxpayer dollars cannot be made more available to benefit community, rural and public hospitals. It is also unfortunate that improvements in VistA that have been made in the private sector in the past two years cannot be given back to benefit the VA.

To address these two issues, I urge the Committee to consider redirecting 5% of the funds annually appropriated to the VA for research and development of VistA for 5 years to create a public-private partnership whose purpose would be to promote the use of VistA by supporting the open source development of the VistA code, bi-directional sharing of enhancements, interfaces with proprietary systems (especially legacy back office systems), standards of interoperability where needed, and validation of improvements so that this public domain product could benefit both government and private health care providers.

At the end of 5 years, the partnership should be expected to be self-sufficient. Even before that time VA should be able to realize substantial benefits from improvements to VistA that should obviate much of its need for software development funds to support VistA. This should result in much lower IT funding needs for the VA on an ongoing basis.

This relatively small initial investment should result in marked savings in the long term for VA and IHS.

Given the large number of physicians and other health care professionals already familiar with VistA as a result of their training at VA facilities, the large number of current VA and IHS users of VistA, and the nascent commercial community of VistA users, this public-private partnership could provide the formal structure needed to catalyze widespread adoption of an electronic health record.

Under this scenario, instead of VA being the sole developer of the VistA code, as is now the case, it would become a contributor to the code among a community of public and private users. In this scenario, everyone in the community would be collaborating and contributing to improving and enhancing the VistA code. This arrangement, as an open source project, would enable the VA to leverage its budget, increase collaboration with private sector adopters, and enable a community of users to coordinate their efforts around a common platform. In brief, everyone would benefit under this scenario.

This public-private partnership might be envisioned to function like the Eclipse Foundation currently does in advancing "the creation, evolution, promotion and support of the Eclipse Platform and to cultivate both an open source community and an ecosystem of complementary products, capabilities, and services."[2] Eclipse is a software platform that IBM released into open source in 2004. Other conceptually similar open source collaborative models exist, including the highly successful Apache, Mozilla, OpenOffice and MySQL projects.

Make use of an EHR a Condition of Participation for Medicare

As was seen with hospital reporting on quality metrics a couple years ago, participation in the Medicare program, and even very small changes in Medicare payment rates, can serve as a powerful catalyst to change health care provider behavior.

In this vein, I urge Congress to set a date after which use of an electronic health record will be a condition of participation for health care providers who wish to participate in the Medicare program. Recognizing the need for an adequate lead time before such a requirement went into effect, I would suggest a two phase process.

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[2] Eclipse Foundation Bylaws. *www.eclipse.org*

To be generous, the year 2015 could be set as the year when use of an EHR would become a Medicare condition of participation. However, to encourage more rapid adoption of electronic health records, beginning at an earlier date—say 2011—providers not using an EHR would receive an incrementally lower Medicare payment rate than those who used an EHR. Each year until 2015, the difference in rates would increase.

If such an approach were taken, then Congress would also need to specify what would qualify as an electronic health record. Without getting into elaborate detail here, I would suggest that the core set of attributes necessary to qualify as an EHR include the following:

1. Have functionality across the continuum of care;
2. Be scalable across the continuum of care;
3. Have integrated applications that all access a common data base;
4. Have a comprehensive suite of application functionality;
5. Incorporates standards of coding and interoperability;
6. Is platform (i.e., hardware and operating system) neutral;
7. Has a demonstrated ability to improve quality, safety and efficiency; and
8. Incorporates the national consensus standards for healthcare performance measurement endorsed by the National Quality Forum.

The basic attributes of an integrated electronic health record listed above would no doubt be the subject of considerable debate, and I would urge the Committee to keep them at this general level of specificity—specific enough so that they are meaningful but not so specific that they are prescriptive or anti-competitive.

Conclusion

Madam Chairwoman, as a final comment this afternoon I would again note that I believe the single most important thing that can be done to improve the quality and safety of health care today, and to concomitantly constrain the inexorable rise of health care costs, is to widely implement affordable electronic health records. However, the piece of the health care IT solution that has not been previously adequately considered is open source software.

I believe that the future of health care IT lies in open source solutions, and Congress could do several things, as noted above, to promote the development and adoption of these highly cost-effective alternatives to the currently available proprietary products.

That concludes my testimony. I would be pleased to answer any questions that the Committee might have.

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Chairman JOHNSON. Thank you, Dr. Kizer, and I do appreciate the specificity of your testimony. That is very helpful to us.
Mr. Smith?

STATEMENT OF JOSEPH SMITH, SENIOR VICE PRESIDENT AND CHIEF INFORMATION OFFICER, ARKANSAS BLUE CROSS/BLUE SHIELD, ON BEHALF OF THE BLUE CROSS AND BLUE SHIELD ASSOCIATION

Mr. SMITH. Madam Chairman and Members of the Subcommittee, thank you very much for the opportunity to testify here today. I am Joseph Smith, Senior Vice President and Chief Information Officer for Arkansas Blue Cross and Blue Shield. I am here on behalf of the Blue Cross/Blue Shield Association. I will cover three overall points: first, I would like to highlight how Blue Cross and Blue Shield Plans are advancing health information technologies in their communities across America; secondly, I would like to express support for many key dimensions of H.R. 4157; and, finally, to explain what I think is absolutely critical, that more time be allowed to switch to ICD–10.

With respect to the Blue Cross/Blue Shield Plans, there is a wide variety of initiatives underway to advance health IT across the

country because we believe in health IT's tremendous potential to improve the quality of service and reduce costs. While my formal statement describes many Blue Cross Plans' initiatives, I will focus only on my Plan's implementation of one of the Nation's first statewide health information exchanges.

I am proud to say that while many are now talking about creating an interoperable health information system, we in Arkansas have actually done it and have had important information to share. In 1995, Arkansas Blue Cross and Blue Shield partnered with two major Arkansas hospitals and IBM to create an interoperable network to exchange administrative, financial, and clinical information, with the objective of empowering providers with information at the point-of-service. We also worked with many providers to deploy electronic health records and continue to do so.

This system went live in 1998 and is serving providers well today, although some portions of the clinical functionality had to be discontinued in 2002 due to the lack of provider funding. Our experience in this statewide information exchange provides valuable lessons that we could all use in creating similar systems elsewhere in America.

Secondly, the Blue Cross Plans support key provisions in the health IT bill, H.R. 4157. We strongly support establishing interoperability standards through a public and private collaborative process. The lack of standards was the biggest single challenge we faced in creating the interoperable system in Arkansas.

Thirdly, while we support much of H.R. 4157, we strongly urge the Committee to modify the legislation to allow 3 additional years to switch to ICD–10, with the implementation beginning no sooner than October 2010 and final completion 2012. Extra time is absolutely critical because of the extensive work required for providers and payors, including CMS, to implement ICD–10.

First, the major consolidation of Medicare administrative contractors from 50 down to 15 contractors, the largest single contracting change in Medicare history, must be completed before the contractors can begin on the transition to ICD–10. This is a massive consolidation targeted for completion in 2009 and has by itself the potential for major provider and beneficiary payment delays and inaccurate payments. Laying on another huge system change on top of that, in our opinion, would be an unacceptable risk to the Medicare Program.

Secondly, before implementation of ICD–10 can begin, the industry must move first to the new HIPAA 5010 transactions because the HIPAA 4010A does not accommodate it. Upgrading this is a hugely complex job involving some 850 categories of changes.

Thirdly, physicians and other providers will need time to understand and prepare for the major changes in their practices that will be called for by the ICD–10. Unless these physicians have the support systems in place to perform real-time coding while the patient is still in the office, they will not be able to achieve the benefits from the greater specificity of ICD–10. It is for these reasons and others outlined in my formal statement that we urge the Committee to set a more realistic timeframe to switch to ICD–10. This change is essential if we are to avoid major payment delays that could affect beneficiaries and providers, widespread inaccurate pay-

ments, and increased fraud and abuse potential in both government and private health care programs.

Thank you very much for the opportunity.

[The prepared statement of Mr. Smith follows:]

Statement of Joseph Smith, Senior Vice President and Chief Information Officer, Arkansas Blue Cross Blue Shield, Little Rock, AR

Introduction

Good afternoon. My name is Joseph Smith, and I am Senior Vice President and Chief Information Officer of Arkansas Blue Cross and Blue Shield (ABCBS). I am speaking on behalf of the Blue Cross and Blue Shield Association (BCBSA), which is made up of 38 independent, locally operated Blue Cross and Blue Shield companies that collectively provide healthcare coverage for 94 million—nearly one-in-three—Americans.

On behalf of the Blue Cross and Blue Shield Association, I would like to thank you for the opportunity to testify on progress currently being made through BCBS Plans' efforts to increase adoption of health IT, and on areas where specific legislative changes may be required.

Blue Cross and Blue Shield Plans are committed to a health care system that delivers safe, efficient, and high-quality care for consumers—giving consumers greater value for their health care dollars—as well as increased administrative efficiency for providers, payers, government, and consumers. Achieving this goal requires nationwide adoption of health information technology (IT) that is based on interoperability standards that support the exchange of clinical and administrative information among providers, payers, government, and consumers, and that includes the tools providers need to deliver high-quality, evidence-based health care.

My testimony will focus on three areas:

I. **Our efforts to increase adoption of health IT,** such as Arkansas BCBS's initiative to promote statewide health information exchange, the Advanced Health Information Network (AHIN).

II. **Our support for the provisions in H.R. 4157** to develop, approve, certify, and inspect standards for electronic health information, and to move towards a single set of national standards to preserve and protect the security and confidentiality of personal health information.

III. **Our recommendation for a realistic timetable to switch from the ICD–9 code set to ICD–10.** The October 2009 compliance date in H.R. 4157 is not workable. We fear it would lead to payment delays and inaccurate payments in both Medicare and in private health care programs.

I. Blue Cross and Blue Shield Plain Initiatives to Increase Health IT

To further the goal of health IT adoption, BCBS Plans are generally carrying out four basic, often interrelated strategies. Plans are:

- Helping physicians adopt and use new technologies such as electronic prescribing (e-Rx).
- Creating payer-based electronic health records (EHRs) for physicians.
- Empowering consumers with Personal Health Records (PHRs).
- Partnering with other stakeholders to enable the statewide exchange of information, and in the process creating a clinical interoperability normalization process.

Helping Providers Adopt New Technologies

Many BCBS Plans are helping providers adopt technology, particularly in the area of electronic prescribing. Electronic prescribing, or e-Rx, promises to improve patient safety and save money, in part by boosting use of generics and compliance with formularies. Some estimates claim that nationwide adoption of e-Rx could eliminate as many as 2.1 million, or close to one-fourth, of the annual adverse drug events per year.

Typically, Plans help providers in one of two ways. First, some offer incentives to use electronic prescribing tools, such as giving physicians $250 to enroll and sign contracts with one of a list of approved e-prescribing system vendors and another $250 if a six-month review shows they are doing at least some e-prescribing. Second, some offer electronic prescribing tools directly, such as providing handheld electronic prescribing technology (hardware and software) to high-prescribing physicians.

I would note that virtually all Plan efforts to help providers acquire technology could be inadvertently threatened by the way the new safe harbor is constructed under H.R. 4157—I will elaborate on this concern later in the testimony.

Creating Payer-Based Electronic Health Records for Physicians

Several BCBS Plans have developed a payer-based electronic health record (EHR), a record compiled from claims data submitted by providers to health plans: diagnoses, procedures, medication history, lab history, lab results, etc. What makes payer-based EHRs particularly exciting is that health plans are generally the only stakeholder in the health care system that collects information from almost all providers that their members visit and, therefore, the only stakeholder that can give a physician a cross-provider view of a patient's history.

The utility of payer-based EHRs has been vividly illustrated in the states affected by last year's devastating hurricanes. By mining their large bases of electronic data—continually gathered through care management programs and claims payments over time—the Plans in the affected states were able to create payer-based health records for all the members who were affected by Hurricanes Katrina and Rita. This record chronicled a patient's comprehensive health plan record, including every medical treatment, lab test, medication and related service that had been paid for by the individual's Plan.

Empowering consumers with Personal Health Records (PHRs)

The Personal Health Record (PHR) is a set of tools that will allow consumers to access their electronic health information and to make certain information available to caregivers. Nearly all Plans are responding to increased interest among employers and consumers in a PHR capability that enhances consumers' ability to make decisions. Most development efforts have focused on a consumer-centric model with member control of PHR content and access to information by other parties (e.g. provider, Plan).

The need for PHRs was especially compelling in the aftermath of Hurricane Katrina. BCBS LA saw PHRs as a way to help the more than 250,000 of its members who were displaced, many of whom did not have access to their medical histories. Drawing from claims-based information, the Plan created an easy-to-understand summary of the patient's health conditions combined with treatments associated with these conditions. Members could call the Plan's Customer Service Call Center to request their claims-based health records. After verifying the member's identification, the Plan would e-mail, fax, or mail the record to the member. Members will soon be able to access the information via secure portals on the Plan's website.

Enabling Statewide Health Information Exchange

With a local presence in each and every state, BCBS Plans are keenly interested in promoting interoperability among key stakeholders. Arkansas BCBS exemplifies this interest, having developed what we believe is one of the nation's first, fully-operating statewide health information exchange, the Advanced Health Information Network (AHIN).

Background on AHIN

In 1995, an Arkansas-based consortium undertook the creation of one of the nation's first provider and payer interoperable networks to include administrative, financial, and clinical information, with the objective of empowering health care professionals with information at the point of service. The Advanced Health Information Network (AHIN) was built by a partnership of Arkansas BCBS, two of Arkansas's major hospitals (St. Bernards and St. Michaels) and the IBM Corporation in accordance with a set of guiding principles. Key among these principles were the following;

- The patient/member is the epicenter of the architecture in that all actions revolve around individual members or patients.
- A global as opposed to an organizational view of the health care industry.
- Leverage existing IT investments wherever possible.
- Provide options for integration wherever possible.
- Create a virtual secured view of the member/patient record via a Master Patient Index.
- Build upon industry standards, primarily ANSI and HL7.
- Create open systems that would not be burdened by only one tool or vendor.
- While designed for Arkansas, architect the system for portability so that it could be used anywhere.

In addition to creating and deploying AHIN with our partners, Arkansas BCBS has worked with providers since 1996 in deploying Electronic Health Record (EHR) systems to connect with AHIN in order to facilitate interoperability. To date, more than 1,000 EHR licenses have been deployed, primarily in larger clinics. In addition, we have recently successfully piloted a wireless EHR for smaller rural physician settings at a price point sought by AHIN's strategic vision.

The AHIN is built on a distributed architecture model. The foundation for the system is a Master Patient Index (MPI) which contains what we call Global Member Data. Global Member Data are not composed of the actual records relating to specific patients but descriptions of the type of data and pointers to where the data actually reside. Linking all of the data about a specific patient together is a Universal Patient Identifier (UPI). The architecture of the system includes a Central Hub where the MPI resides.

A great deal of effort went into making this system as secure as technology would allow. In addition, because of state privacy laws, it was necessary to suppress certain types of clinical information such as mental health treatment or data relating to sexually transmitted diseases. A combination of special protocols and processes, effective firewalls, intrusion detection systems, careful management of passwords and usage auditing offers a highly secure environment.

The system moved from concept to "beta" operation in 1998, and then continued in operation intact for more than two years in two regions of Arkansas. While the system worked very effectively, in 2002 portions of the clinical system functionality were discontinued due to a lack of provider funding. However, the remainder of the system was retained and expanded and today AHIN serves virtually all providers in the state of Arkansas with administrative and financially-related functionality.

Lessons Learned from AHIN

Arkansas BCBS's experience with the AHIN imparts some valuable lessons learned for other communities that are considering a health information exchange network:

- **Normalizing exchanged clinical data is the biggest single challenge—**it takes considerable and continuous effort to take data elements from several organizations and put them into one common data dictionary to normalize the data across all stakeholders. This challenge underscores the importance of accelerating standards, as I will discuss below.
- **All interacting stakeholders must be at the table—**developing a shared vision, and a set of strategic guiding principles, is essential to helping overcome the invariable rough patches.
- **A global member index/ID is "required" to link interoperable records—**patient identification and matching of data from disparate systems is an integral part of what the AHIN does. We found that while Patient Matching Algorithms generally work very well for patient identification, they can be vulnerable to errors when data changes, as it often does (such as last name changing as the result of marriage or divorce). This has taught us that without some sort of static identifier which can be used internally, identifying a specific individual with a probabilistic algorithm is much less a sure thing.
- **EHR deployments need to be carefully integrated into providers' practice settings—**if physicians believe that an EHR deployment is disruptive to their daily workflows, then health IT adoption will be severely limited.
- **Finally, common, non-proprietary standards are essential—**efforts such as the AHIN will be facilitated by established industry standards for data formats, content, and transmission protocols. These standards cannot be proprietary. Allowing various vendors to either dictate their preferred/proprietary data formats or protocols, or to become intermediaries or clearinghouses would hold other stakeholders hostage.

II. BCBSA Support for Provisions in H.R. 4157

Legislative changes included in H.R. 4157 will go far to help efforts like the Advanced Health Information Network. Lack of interoperability standards to enable physicians, hospitals, and payers to exchange clinical information has been a major barrier to wider health IT adoption.

We strongly support establishing interoperability standards through a public-private collaborative process. The bill's requirement that the government, to the maximum extent possible, contract with or recognize private entities in developing, approving, certifying, and inspecting health IT standards is an appropriate position in our market-driven economy.

Uniform Privacy Standards

We also share H.R. 4157's concern about the effects of varying state and federal privacy laws on the ability to exchange personal health information securely and confidentially in a national health information network. Without Congressional action, medical providers attempting to work together through interoperable health information technology systems would be subject to a confusing maze of state laws, rules, and regulations. H.R. 4157 offers an appropriate solution to this issue by allowing a state law study to be conducted first to determine the best way to achieve uniformity. If Congress fails to act upon the recommendations produced from the study, then HHS is charged with developing a uniform rule based on HIPAA. Importantly, these provisions provide a course of action and ensure that a national standard will be achieved.

Safe Harbors

While we appreciate the need to address the current federal anti-kickback/anti-fraud statutes, we are concerned (as mentioned earlier) that the new exception/safe harbor in H.R. 4157 could inadvertently have a chilling effect on health plans' current programs to help providers acquire electronic prescribing capability.

The problem is that H.R. 4157 only gives protection to non-monetary remuneration that is made without taking into account the volume or value of referrals (or other business generated) by the physician to the entity. However, BCBS Plans' programs to help physicians health IT such as e-Rx commonly target physicians on the basis of volume (number of prescriptions written or the cost of the drugs prescribed). By taking into account volume and value, Plans have the most impact on improving physician practices and improving services provided to the greatest number of health plan members. Prohibiting health plans from considering, for example, the volume and value of prescriptions that are paid for by the health plan would detract from the widely shared goal of promoting electronic prescribing.

We believe that the usual concerns about taking the volume or value of business generated between two parties do not apply to health plans. Unlike other entities covered by the safe harbor, health plans are designed and have every financial incentive to control utilization costs to compete effectively. The incentives of health plans and of the government are aligned by the contractual arrangements to promote gains in efficiency and quality, and to control fraud and abuse.

Therefore, we would recommend amending H.R. 4157 so that the volume-based criterion not apply to health plans when they help providers adopt electronic prescribing capability and other health IT.

III. A Realistic Timetable to Switch to ICD–10

H.R. 4157 calls for switching from the current ICD–9 code set for diagnoses and hospital inpatient procedures to the more granular and precise ICD–10 code set by no later than October 2009. This timeframe is not workable

We urge the Committee to extend the compliance date by three years, with implementation beginning in 2010, and final compliance in 2012. Three additional years are needed because:

- It would be hugely risky to implement ICD–10 at the same time that CMS is conducting the largest contracting change in Medicare's history, the consolidation of Medicare administrative contractors from 50 to 15 contractors.
- Industry must first upgrade all ten HIPAA transactions from the current 4010 version—which cannot handle ICD–10—to a new 5010 version. At the same time, the government must create, and industry must analyze and refine, backward and forward electronic crosswalks between ICD–9 and ICD–10.
- Physicians and other health care professionals will need adequate time to understand and prepare for the major change in their practice that will be called for by ICD–10.
- All stakeholders will need to participate in and learn from a pilot before rolling out a nationwide implementation.

The transition from ICD–9 to ICD–10 will be a massive undertaking. Provider and payer systems must be completely redesigned to handle hundreds of thousands of new codes at an estimated cost of up to $14 billion. Providers process and store diagnosis and procedure codes in virtually every one of their computer systems, many of which are linked to share information. Payers use diagnosis and procedure codes not only to process claims, but also to design benefit packages, construct fee schedules, operate disease management and quality improvement programs, make medical necessity determinations, and prevent fraud and abuse. Three additional years is essential to avoid costly mistakes and disruptions in claims payments.

Medicare Contractor Reform

To meet an ICD–10 compliance date of October 1, 2009, payers would have to start implementing ICD–10 in 2007. However, over the same period, CMS is conducting the largest fee-for-service contracting change since Medicare's inception: more than 50 fiscal intermediary and carrier contracts will transition to 15 Part A/ B Medicare Administrative Contractors (MACs).

Contractor reform is currently fraught with risk because of the volume and complexity of claims workload transitions. The MAC transitions will be more complex than past contractor transitions because both Part A and Part B workloads will be transferred from multiple contractors to a single MAC in a new jurisdiction.

In an August 2005 report, the General Accountability Office (GAO) raised concern that CMS has not developed an approach that fully integrates the planning and scheduling of Medicare contracting reform with other initiatives that will affect Medicare contractors, beneficiaries, and providers over the next several years, such as the Medicare prescription drug benefit, the expanded Medicare Advantage program, and several major systems upgrades or replacements—not including ICD–10.

This massive consolidation, involving more than 1 billion Medicare claims, by itself has the potential for major provider and beneficiary payment delays and inaccurate payments. Attempting complex transitions of almost all of the claims administration workload in less than 2 years, in conjunction with changes in the data centers and financial management systems (not including ICD–10), significantly increases the risk that providers' claims will be paid improperly or not be paid at all. Layering another huge systems change on top of consolidation would raise risks exponentially.

HIPPA Maddated Transaction

Before anyone can switch to ICD–10, industry must upgrade all ten HIPAA transactions to a new version (version 5010) because the current version (4010) will not work with ICD–10. This is a major upgrade (a "re-architecture of the HIPAA standards). Industry needs version 5010 not only to handle ICD–10 codes, but also because the current transaction standards are increasingly out of date. The 4010 version standards were developed in 1998, and the implementation guides that were initially adopted for HIPAA were written in 2000. Over the last 8 years, the Accredited Standards Committee X12 has made numerous changes to the original transaction standards that have not yet been made available to the industry via adoption under HIPAA.

The implementation guides for version 5010 are not yet available. At an NCVHS hearing this week, the Chair of X12, the standard-setting organization responsible for version 5010, released an estimated schedule for the version 5010 implementation guides (also known as Technical Report 3's)—as an estimate, all the dates are subject to change as the implementation guides go through their reviews with the public and technical committees at X12. The dates in the chart below represent when X12 anticipates submitting a change request to the Designated Standard Maintenance Organization (DSMO).

Transaction	Date of Submission
1. Remittance	May 2006
2. Professional claim	June 2006
3. Institutional claim	
4. Dental claim	
5. Services review	
6. Plan enrollment	September 2006
7. Plan premium payment	
8. Claim status inquiry/response	
9. Eligibility inquiry	December 2006
10. Eligibility response	

Source: Statement of the DSMO to NCVHS, April 4, 2006.

It will take approximately four to five months from that date—under the time-frames allowed by the DSMO Memorandum of Understanding—before the National Committee on Vital and Health Statistics (NCVHS) is contacted with a finalized change request. Thus, even before the rulemaking process begins with its notice and comment period, payers, providers, and vendors will have to wait until May or June of 2007 for the complete set of version 5010 implementation guides.

H.R. 4157 seeks to accelerate the process of implementing version 5010 by waiving the notice and comment period. While we agree that the process for adopt-

ing HIPAA standards needs to be streamlined, we think it is essential that CMS keep the notice and comment process.

The notice and comment process is industry's primary opportunity to raise business issues that have broad policy implications. To take claims attachments as an example: the SDO might focus on the business requirements around a specific interaction between trading partners such as an unsolicited claim attachment; but CMS would focus on the larger issue of whether or not to allow unsolicited claims attachments. Only the agency's comment and review process gives industry the opportunity to consider the proposed mandate from an enterprise or industry-wide perspective. We believe that global perspective review is essential for the industry and we strongly believe that global review opportunity must be preserved under any revised system for HIPAA changes.

Whatever the date that the 5010 version is approved for all ten HIPAA transactions, it will take industry the full two years allowed under HIPAA because the changes from the current version are voluminous—more than 850 individual changes—and complex. Users will have to analyze each change's potential impact on the systems that generate required data for transactions; the systems that create the standards transactions; the systems that convert standard transactions to internal formats; internal processing systems, and business processes.

During the time that industry is implementing a new architecture for the HIPAA transactions, it would not be feasible to convert to the more complex ICD–10 coding scheme.

One reason is that the administrative overhead associated with an overlapping implementation would be enormous. During the transition to version 5010, payers and providers will each need to operate dual processing systems: one to process 4010 transactions for day-to-day operations, and one to process 5010 transactions for analysis and testing purposes. If the transition to ICD–10 overlaps with the transition to version 5010, payers and providers will need to operate *triple* operating systems: one to process 4010 transactions, one to process 5010 transactions with ICD–9, and one to process 5010 transactions with ICD–10.

Another reason is that an overlapping implementation would violate a basic tenet of systems design: implement and test one major systems change at a time. It is critical that the version 5010 transaction standards are stable before payers and providers begin analyzing and testing other significant changes. If version 5010 and ICD–10 implementations were to overlap, and testing revealed problems in any of the dozens of internal systems and applications affected by 5010 and ICD–10, it would be extremely difficult to determine the source of the problem: preparation/implementation of 5010, or preparation/implementation of ICD–10. The operational problems that 5010 was designed to correct will be unnecessarily prolonged if payers and providers are forced simultaneously to implement ICD–10.

Keep in mind that upgrading to version 5010 is not the only HIPAA-mandated activity occurring over the next couple of years. Payers and providers are currently working hard to implement the national provider identifier—a massive effort to assign a unique code to every provider for all health plan transactions—by May 2007. Other major, costly HIPAA mandates on the horizon include standardized transactions for six types of electronic claims attachments, and the national payer identifier, all of which would require the same staff resources as would be required to implememt ICD–10.

Crosswalks

During the transition—and perhaps for some time after—both payers and providers will need backward and forward electronic crosswalks between ICD–10–CM and ICD–9–CM diagnosis codes, and between ICD–10–PCS and ICD–9–CM procedure codes. Backwards crosswalks (from ICD–10 to ICD–9) will help payers and providers bootstrap themselves into the new codes, permitting users to schedule major systems changes in an orderly sequence. Forward crosswalks (from ICD–9 to ICD–10) are indispensable for creating links between historical ICD–9 data—such as a clinical work flow process maintained by a provider, or a payer's time series of claims data used to build fraud and abuse edits—and new ICD–10 data.

Currently, backward and forward crosswalks are available only for ICD–9/10 procedure codes, not for ICD–9/10 diagnosis codes. In fact, the final ICD–10–CM code set is itself not yet available. All that is available on the website of the National Center for Health Statistics (NCHS) is the 2003 pre-release version of ICD–10 diagnosis codes. NCHS is hoping to issue a final version of ICD–10–CM by the end of the fiscal year, but even then crosswalks may not be ready.

Building crosswalks between ICD–9 and ICD–10 is but a first step. As other countries using ICD–10 have learned, mapping is an inherently imperfect science in that most relationships involve one to many mappings, and forward and backward

mappings may not synchronize. Indeed, the forward (ICD–9 to ICD–10) crosswalk recently published by CMS underscores the ambiguity inherent in a one-to-many crosswalk: "The map [ICD–9 to ICD–10] contains possible options from which the appropriate ICD–10–PCS code can be chosen, depending on the use to which the map is put."

For example, CMS maps the ICD–9 code for the procedure "Infusion of recombinant protein" (00.11) to 12 potential ICD–10 procedure codes where the infusion of recombinant protein varies depending on the mode of infusion (open or percutaneous) and on the site of infusion (central vein, peripheral artery, central artery, coronary artery, heart). In practice, it would be impossible for a provider or payer to map longitudinal data on 00.11 to ICD–10 codes with any certainty.

This ambiguity is why the Rand Corporation recommended giving serious thought to having a major provider code diagnoses and procedures in both ICD–9–CM and ICD–10–CM/ICD–10–PCS to determine which codes are interpreted similarly. Rand noted that this process would help to develop a crosswalk between ICD–9–CM and ICD–10–CM/ICD–10–PCS *in practice as well as in theory* [emphasis added]. It would also help analysts who work with time series interpret before-and-after changes in health statistics. This is where pilot testing could play a vital role: to help translate theoretical crosswalks into practical crosswalks.

Preparing Physicians and Other Health Professionals

H.R. 4157 does not call for replacing CPT codes, which Medicare and other payers use to reimburse physicians' services. Nonetheless, all providers will be impacted by H.R. 4157 because all claims for reimbursement—outpatient as well as inpatient—must include ICD diagnosis codes.

The ICD–10–CM diagnosis code set is much more complex than ICD–9–CM: ICD–10–CM has 120,000 unique codes, almost ten times as many as ICD–9–CM. The accuracy of codes for diagnoses (as well as for procedures) will depend on the precision and specificity of physician documentation. Poor physician documentation will prevent reaping any benefits from the greater specificity of ICD–10–CM.

The slide attached at the end of the testimony illustrates the adjustments physicians will have to make in how they code. Today, doctors just indicate one code for asphyxiation. Under ICD–10, they will need to determine precisely which of the nearly 40 codes created for asphyxiation best describe the case at hand. This demonstrates that physicians will need software literally on their desk to go through the decision tree necessary to identify the correct coding. They cannot simply enter words into a computer program; they will need to know the specifics of the appropriate code.

Therefore, physicians and other providers will need adequate time to understand and prepare for the major change in their practice that will be called for by ICD–10. They will need time to acquire and become proficient with technology needed to sort through and triage the numerous decisions necessary to code properly so they can be paid accurately and timely. The transition to ICD–10 will impact every physician, every day, at virtually every encounter, requiring that they capture additional data they may not even think they need to capture today.

Physician and other provider readiness for effective use of ICD–10 cannot be underestimated. Unless physicians have the support systems in place to perform real time coding, while the patient is in the office, and the commitment to spend the time needed to discern among the greatly expanded choice of similar—but more granular—codes, the investment of billions of dollars will not produce the much anticipated information (e.g., to improve quality). If physicians are not prepared, through use of technology, to support the process of identifying the more refined codes, they may resort to using "default" codes, providing no more specificity than under ICD–9.

Pilot Testing

Adequate pilot testing is crucial to ensure the new system works, providers are educated, and claims will be paid.

A key lesson from HIPAA is the importance of pilot testing to avoid costly mistakes and assure smooth implementation. The final HIPAA rule called for full compliance with these electronic transactions and code sets standards by October 16, 2002. However, Congress decided to extend this deadline for one-year, to October 16, 2003, in part because of serious delays arising from glitches in the standards—glitches that might have been discovered and fixed ahead of time with a pilot. As the 2003 date neared, CMS realized that many providers would still not be in compliance, and so CMS authorized Medicare and private payers on a "contingency basis" to continue accepting HIPAA non-compliant claims as well as compliant claims. CMS only ended contingency operations for Medicare last October, and three

years after the original deadline some private payers are still running contingency operations.

We believe that pilot testing ICD–10 would provide an analysis of the implementation issues facing health plans and providers, including validity of ICD–9/ICD–10 crosswalks, outreach/training, claim adjudication system integration, clinical-administrative system integration, and workflow/process adaptations. The pilot would assess the impact on claims payments, including a comparison to transactions handled with ICD–9, and document any early benefits of the coding system. The pilot would help to prepare payers and providers for implementation, give CMS an opportunity to fix problems in training, education, crosswalks, etc., before nationwide implementation.

The pilot test we envision would involve a Medicare contractor, three or four hospitals representing a distribution of size and clinical activity, two large physician group practices, and a number of smaller physician practices. If CMS were to begin planning today, a pilot could be up and running in the period from 2007 to 2008, leaving sufficient time for an independent evaluator to compile data, conduct comparative analyses, develop lessons learned, and report findings that would inform the later rulemaking process. Indeed, we believe that starting a notice and comment period before a pilot would be counterproductive because industry would be offering comments in the abstract. Far better to have actual facts and lessons learned from a pilot for industry to respond to in comments to CMS.

Conclusion

In conclusion, we believe that widespread use of health IT can save lives, improve quality, and increase efficiency. BCBS Plans are doing their part to increase health IT adoption: helping providers adopt health IT; giving providers access to comprehensive information in payer-based EHRs; developing tools to help consumers manage their own care better through PHRs; and developing statewide health information exchange networks.

We wholeheartedly endorse Congressional action that would help private sector efforts to increase health IT adoption. For that reason, we endorse the provisions in H.R. 4157 to develop, approve, certify, and inspect standards for electronic health information, and to move towards a single set of national standards to preserve and protect the security and confidentiality of personal health information. However, we urge you to adopt a realistic timetable to switch from ICD–9 code to ICD–10, with a final compliance date no sooner than 2012.

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Chairman JOHNSON. Thank you, Mr. Smith.

Ms. Bryant?

STATEMENT OF GLORYANNE BRYANT, CORPORATE DIRECTOR FOR CODING AND HEALTH INFORMATION MANAGEMENT COMPLIANCE, CATHOLIC HEALTHCARE WEST, SAN FRANCISCO, CALIFORNIA

Ms. BRYANT. Thank you. Chairman Johnson, Congressman Stark, and Members of the Subcommittee on Health, good afternoon. I am Gloryanne Bryant, Corporate Director of Coding and Health Information Management Compliance with Catholic Healthcare West. We are based in San Francisco.

I am here today to urge you to quickly move forward with legislation introduced by Chairman Johnson, the Health Information Technology Promotion Act, so our health care industry can make use of the best possible disease and procedure classification systems as soon as possible.

I have been involved in coding and the management of coded data for over 27 years now, and I want to share with you my knowledge, expertise, and vision with my testimony.

Since 1993, when NCVHS declared our United States disease and procedure classification system, ICD–9–CM, "broken," my interest and involvement have been intense. I have provided input in

the replacement of the class system, tested ICD–10, tested the training of coders with ICD–10, developed a planning, implementation, and training project overview of ICD–10 for my health care system, which has led me to multiple lectures on this issue. The following are some key points I want to share.

ICD–9 is broken and obsolete. ICD–10 is needed to improve the quality of health information. Specificity equates to precision, not complexity. ICD–10 is needed to support the electronic health record and the national health information network. Action has to now not been where we could receive the benefits of improved data. This will not be achieved in our lifetime, possibly, or the end of this decade unless we move forward.

ICD–10 classifications are necessary for quality care monitoring, pay for performance, and other areas of health care accountability. Both ICD–10–CM and ICD–10–PCS have been maintained since they were originated. The update for ICD–10–PCS was recently announced in the Federal Register. The update to ICD–10–CM is due in June. The mapping between ICD–9 and ICD–10–CM will also be forthcoming shortly from the Center for Disease Control/National Center for Health Statistics.

It is difficult to measure quality of care or provider performance in addressing the risk factors and effectively treating a patient's condition if the relevant diagnostic and procedural code information includes multiple conditions. For example, if two conditions with different treatment protocols are assigned to the same code, which occurs with ICD–9, how will we evaluate the provider's performance in treating one of these two conditions? Capturing severity can also be an issue. If all we know is that a patient has a decubitus ulcer and not whether it includes the skin or extends down to the bone, we are not able to measure the effectiveness of wound care management programs or the cost of treating that decubitus ulcer. It is obviously more difficult and expensive to treat a deep ulcer than a superficial one. Clinical data specificity like that in ICD–10 can provide the window to quality and performance. I have details examples of diabetes and similar non-Hodgkin's lymphoma examples in my written testimony.

ICD–9 codes are too general, ambiguous, and not reflective of modern medicine. ICD–10 improves the situation by expanding the Codes that are used as part of the quality indicators and are for medical complications and medical safety issues. The specificity in ICD–10 allows for the improved capture of information used for quality measures, pay for performance, and to assess the effectiveness of medical error prevention programs.

It is important to note that medical specialists helped to create the specificity that exists in ICD–10 to capture the necessary data for performance measures and evidence-based medicine protocols. Medical necessity and infections are two other areas of health care that is of interest to the Subcommittee. This is further explained in my written testimony, along with the impact on research, trauma registry, fraud and abuse, and personal health records.

This is a small world. Daily we hear reports of outbreaks, avian flu and the potential for pandemic outbreaks. Currently, the United States would have difficulty with tracking and monitoring pandemic outbreaks of disease or infection for a range of reasons, one

of which is the lack of specific coded clinical data. Does the United States have a diagnostic code for avian flu? Does the World Health Organization have such a code? Yes, with ICD–10.

Does the United States have codes for West Nile virus, SARS, and potential bioterrorism, as with anthrax? We now do, but we did not have them at the time of these events. It took the United States a significant amount of time to develop the necessary codes.

So, why is the United States behind? The United States is not on the same ICD-based system with most of the world, including most other industrial nations. They have converted to ICD–10 while we continue to linger and plod along with a system that was designed and was implemented back in the seventies and is no longer supported by the World Health Organization.

I see a day with my health organization where we can send a claim and have it quickly and accurately processed because the information needed is all contained within the ICD–10 codes. Additionally, the claim information can be confidently used for pay for performance, quality, and injury monitoring. I see a day when public health and researchers can share data internationally in the form of ICD–10–based codes for tracking and monitoring for public health and bioterrorism events.

We are not using the same electronic tools and devices that we bought 10 years ago, let alone 20 years ago, with our health care data system. It is amazing to me that some of us feel comfortable using the same 30-year-old data system. I cannot stress enough the need to upgrade ICD–10 by 2009. We have the most technologically advanced health care system in the world, but it is handicapped by this archaic process with procedures of updating versions of a classification system. We would not do this to Bill Gates and Microsoft. Why do we do this to health care and slow us down? We need to make progress.

I congratulate Chairman Johnson and the Subcommittee for providing leadership on this issue, and I would be pleased to answer any questions that you might have or point to my professional association, the American Health Information Management Association, for responses also.

[The prepared statement of Ms. Bryant follows:]

Statement of Gloryanne Bryant, Director, Catholic Healthcare West, San Francisco, CA

Chairman Johnson, Congressman Stark, members of the Health Subcommittee, ladies and gentlemen, good afternoon. I am Gloryanne Bryant, corporate director for coding and Health Information Management (HIM) compliance with Catholic Healthcare West (CHW). I speak to you today not only from my position at CHW, but also as one of 50,000 health information management professionals throughout the country and industry who are interested in quality information for quality healthcare.

I am here today to urge you to move forward with legislation introduced by Chairman Johnson, HR 4157, the "Health Information Technology Promotion Act." Specifically, I am here to ask you all to support HR 4157 and ensure this bill is acted upon with deliberate speed so our healthcare industry can make use of the best possible disease and procedure classification systems as soon as possible.

I have been involved in the coding and management of coding of healthcare data for over 27 years. Since 1993, when the National Committee on Vital and Health Statistics (NCVHS) declared our U.S. disease and procedure classification system the International Classification of Diseases, Version 9, Clinical Modification (ICD–9–CM) "broken," I have been involved with several of the groups that provided input for the replacement of this classification system.

In the late 1990s, I was a tester of the ICD–10–PCS (procedure coding system), the classification system anointed to replace the existing inpatient procedure codes in ICD–9–CM. It was a successful test and the ICD–10–PCS system has been maintained and ready to go since that time.

In recent years, I have been involved with the testing of the ICD–10–CM (ICD–10–CM) classification system for diagnoses. This testing not only proved the accuracy of the classification system, it also showed how simple the training for ICD–10–CM and ICD–10–PCS could be. This testing was done with the American Hospital Association (AHA) and my professional association the American Health Information Management Association (AHIMA), and the test report is available on the AHIMA Web site. I have also participated in meetings of the ICD–9–CM Coordination and Maintenance Committee, which is charged with overseeing the existing ICD–9–CM. All this activity has given me significant insight on the needs, issues, and problems surrounding the upgrading of ICD–9–CM.

Working with ICD–9–CM on a daily basis reaffirms that it is outdated, broken, inefficient, and nothing but an albatross to our healthcare system. I strongly support upgrading ICD–9–CM to ICD–10–CM and ICD–10–PCS. Yes, upgrading our coding system will require change, but change that is not insurmountable.

Working closely with other professionals at Catholic Healthcare West, I have developed a three year transition plan for CHW to use for the planning, implementing, and training that will need to occur with any upgrade. I have also educated my own staff and others about ICD–10–CM and ICD–10–PCS, the actual use of ICD–10 classification, and the important issues of planning, implementation, and training. You have to understand that the training materials we use today will be considered quite crude once the go-ahead is indicated for ICD–10 classifications. Even so, the coders I have trained have found the ICD–10 systems easy to use, and it enables them to present a complete and accurate report.

The Following some key points I want to share:

- ICD–9–CM is obsolete and the new version, ICD–10, is ready for implementation.
- ICD–10–CM and ICD–10–PCS, the ICD–9 upgrades, are needed to improve the quality of health information. Specificity equates to precision, not complexity.
- ICD–10 is needed to support interoperable electronic health records (EHRs) and a nationwide health information network (NHIN).
- Action has to occur now so that we can receive the benefits of this improved data by the end of this decade.

It is my intention to provide you with the necessary information on the benefits of ICD–10–CM and ICD–10–PCS to move ahead with HR 4157 so we can achieve the benefits these classification systems provide and better the healthcare of all individuals.

Why is ICD–10 necessary for pay-for-performance, accountability, quality reporting, and more?

Quality and Pay-for-Performance

I was asked to address why the ICD–10 classifications are necessary for quality of care monitoring, pay-for-performance, and other areas of healthcare accountability.

Increased detail and better depiction of severity allows improved linkage between a provider's performance and the patient's condition and a better ability to measure quality. It is hard to measure quality of care, or a provider's performance in addressing risk factors and effectively treating a patient's condition, if the relevant diagnostic or procedural code includes multiple conditions. For example, if 2 conditions with different treatment protocols are assigned to the same code, how will we evaluate the provider's performance in treating one of these 2 conditions? Severity can also be an issue—if all we know is that a patient has a decubitus ulcer, and not whether it involves skin only or all the way down to bone, how will we be able to measure the effectiveness of a wound management program—or the cost of treating decubitus ulcers? It is obviously much more difficult, and expensive, to treat a deep ulcer than a superficial one.

Many quality measures, such as HealthGrades and AHRQ's quality indicators, rely on ICD–9–CM codes. If these codes are too general or ambiguous, or not reflective of modern medicine, it will be impossible to produce accurate quality reports or pay providers accurately for performance. Situations have already occurred whereby hospitals have complained about erroneous quality conclusions based on ambiguous or poor ICD–9–CM codes—for example, if a code includes conditions that have variable quality implications (i.e., some conditions don't indicate a quality

problem and other conditions do, but both sets of conditions are classified to the same code, the conclusion, or assumption, often goes to the worst case scenario—i.e., if you can't distinguish which condition the patient had, assume he had the condition with the adverse quality implication and "ding" the provider).

ICD–10–CM greatly expands the codes for medical complications and medical safety issues—allowing for much better capture of this information for use in quality measurement, P4P, and to assess the effectiveness of medical error prevention programs.

Also, if there is a disconnect between the outdated classification of a condition in ICD–9–CM and the modern clinical classification of a disease process, it is difficult to relate modern treatment protocols and performance measures to the relevant code in ICD–9–CM (it is like comparing apples with oranges—current performance measures and evidence-based medicine protocols are linked to a diagnostic structure or diagnostic or procedural distinctions that do not exist in ICD–9–CM).

It is difficult to evaluate the outcomes of new procedures and emerging healthcare conditions when precise codes are lacking. For example, in ICD–9–CM, many procedures are not differentiated by approach. For basic quality measures such as mortality, rates can vary widely depending on the approach used.

CMS has even acknowledged that it would be difficult to implement a severity-refined DRG system without ICD–10 because the inability to collect a finer level of detail would limit the usefulness of the DRG refinements.

ICD–10–CM will open new opportunities in injury research and trauma services evaluation. To further research in the area of prevention and treatment of injuries, we must be able to more accurately classify the nature of the injuries sustained and correlate the nature of injury with the mechanism of injury, treatment, and outcome. ICD–10–CM will provide a much-improved ability to accomplish this task. Major improvements relative to injury prevention and treatment include: addition of a 6th character that expands the flexibility of the system and allows for incorporation of more specific injury codes; separation of many previous "multiple injury" codes into separate codes and elimination of certain "illogical" injury codes, especially with regard to head injuries; incorporation of terminology commonly used by clinicians; inclusion of laterality code which affords the opportunity to identify bilateral injuries and provides an unprecedented ability to more accurately study patterns of injury and how they relate to the underlying mechanism of injury.

The improvements in ICD–10–CM have important implications for our ability to rate severity of injuries. Several different classification systems are being used by trauma clinicians to rate severity of injuries for the purpose of benchmarking, quality improvement activities, and research. These systems require an independent review of the medical record, which is becoming increasingly cost-prohibitive. The use of ICD–10–CM as a basis for rating the severity of injuries would obviate the need for these alternative scaling systems.

ICD–9–CM lacks specificity regarding the extent of injury and uses terminology and severity parameters that are either outdated or inconsistent with other widely used clinical classifications. ICD–10–CM would address many, if not most, of these inadequacies and bring us closer to a universal classification of injuries.

While some criticize the size of the ICD–10 code sets or the number of codes available for use, these code sets have been expanded from ICD–9–CM to reflect 21st century medicine and diseases. They provide the detail needed if healthcare providers are to be paid fairly in the future. Currently, hospitals are supplying quality monitoring data. The only way to get knowledge from this data is to also look at the diagnoses codes that are included on the claim.

This quality data is looked at against diagnoses represented with up to nine codes (codes are limited by Medicare in order to accommodate paper billing), but these are diagnoses codes first renewed (from ICD–8-CM) 30 years ago. Since then, or should I say, since the 1970s, our medical knowledge represented by diagnosis, technology and procedure codes has expanded greatly. Interestingly enough, today's ICD–9–CM classification has to ignore this expansion of healthcare knowledge and treatment because it is running out of the codes necessary to provide the necessary and accurate representation.

In ICD–9, our medical coders find that they are unable to code accurately because the codes available do not have the level of specificity that matches the information and clinical documentation in the health record. In these cases, the coder often has to make use of an ambiguous code, which is frustrating and potentially expensive. When the claim is submitted someone may call back asking for additional detail, which involves getting data from the medical record, copying it, and sending it out.

Accountability is the hallmark of a medical coder. If we do not find the information in the record, we do not code it. Therefore, it is very frustrating to find the information in the record and then either be unable to code it, or have to use either

a vague code or choose between any number of vague codes. In behavioral health, we are forced to use a "cheat sheet" to change record information into acceptable codes. Why? The codes in ICD–9–CM are so far behind the advances in behavioral health that we have no correct codes. Technically, we are not supposed to change codes, but with the blessing of CMS, it is something that we do or we would not get paid.

We have so many requests for additional detail that we have had to hire photocopying companies and other outsourcing resources to handle the requests. This is common throughout the healthcare industry. In addition to the costs and time associated with handling these requests, the plans also incur costs and dedicate employee time. Why? Someone has to read and interpret this information. Then, and only then, is a payment processed. Meanwhile, besides the cost of processing the additional information, an organization also has a cost of carrying a receivable.

Many of these efforts and expenses are incurred because we do not have a classification system that can represent the information that is in the patient's record. The more that we get into sending data for quality monitoring or other reasons—often demanded by Congress—the greater this problem of equity, cost, and accuracy will be.

The collection of quality monitoring data is not the end of the story as we are really just starting this process. Next in line are the pay-for-performance programs. In this environment, the provider is financially affected if there is an issue between the quality indicator and the actual state of the patient's health and procedures, which to judge correctly will mean getting the additional clinical data mentioned previously. Again, without the ICD–10–CM and ICD–10–PCS upgrades, providers are going to expend additional resources to provide health plans with enough data so we get paid accurately under P–4–P. If we cannot improve the content of our codes, we will all lose. It is a vicious cycle and I do not see it changing soon. Each day, more and more information is sought relevant to the claim, and for decades we have neglected to upgrade the crucial clinical information on the claim itself. We need to upgrade to ICD–10.

Medical necessity and infections are two other areas of healthcare that I believe are of interest to this subcommittee. Under medical necessity, a provider has to demonstrate that there is a need for the patient to receive certain care. Again, we are forced to manually process claims to ensure that we send parts of the health records to prove the medical necessity. While moving to ICD–10 classifications will not eliminate this problem, there will be a substantial decrease in the need to review additional parts of the record if the claim can carry more detailed coding—both in the codes used and in the number of codes reported. This problem, which is another resource burner for many hospitals and physicians, could be greatly alleviated with the detail available in the upgrades from ICD–9–CM to ICD–10.

In 2007, hospitals are required to begin reporting "diagnoses present on admission." This data is to provide CMS with information that eventually may lead to some care not being reimbursed—situations where it is deemed the institution's fault that additional care was needed. For instance, was the infection, or other problem, present when the patient was admitted, or did it arise during the stay? While some believe that continuing to use ICD–9–CM is not a problem, it will be clear when conflicts arise due to coding that may or may not be reflective of the details involved with infections or similar issues that arise. If we cannot implement a more contemporary classification system until 2009, it might perhaps be better for Congress delay this requirement until ICD–9–CM is upgraded.

I have repeatedly mentioned using medical records to make up for missing or vague codes. This problem is also becoming more prevalent in the area of medical procedures and technology. A few years ago, Congress asked CMS to ensure it is keeping up with new technology. Again we are running out of codes in the area of inpatient technology and procedures. So, we are merging technologies into essentially group codes, and then, to get proper reimbursement, we are sending additional "attachment" detail to the claims adjudicator.

It has been suggested by some that there are plenty of codes left to describe new technology and procedures. When citing the number of codes, these same critics fail to mention that once we run out of sequenced codes, the ICD–9–CM Coordination and Maintenance Committee will have to assign codes in other chapters (associated with body systems). This will essentially eliminate the ability to monitor such data by computer.

I can mention other areas where the detail in ICD–10–CM and ICD–10–PCS could greatly improve healthcare and its administration by CMS and others. It is important to recognize that the depth of clinical data continues to drive major healthcare decisions, for payers, researchers, regulators and Congress.

I know there is an expectation by some that once we have a standard electronic health record (EHR), we will not need to have such a classification system. However, this suggestion ignores the fact that the detail in the EHR will be too granular to be used for all the secondary purposes that require providers to submit data to the government, health plans and others. Classifications, or the codes that make up the classification system, provide this data and make it usable for a variety of purposes that a copy of the record, paper or electronic, just cannot do. Until we have a good classification system implemented, the value of the EHR development will not be experienced by the patient or the population.

Fraud ans Abuse

I mentioned ambiguous codes. Using ICD–9–CM, coders often have to make choices in codes they assign because there may not be an accurate code for the diagnosis or procedure that is reflected in the record. It is almost like the story of the lady and the tiger. If you make the wrong choice, the tiger—be it the health plan, the Medicare carrier, or the Department of Health and Human Services (HHS) Office of the Inspector General (OIG)—comes out and accuses you of fraud. Some believe more detailed coding system will increase fraud, but I believe exactly the opposite will happen. When we have codes that can actually match the 21st century data in the medical record then we will not have to choose the lady or the tiger. The code needed to reflect the data present will become much easier to ascertain. In fact, ICD–10–CM was designed to eventually allow for what we call "computer assisted coding," where the computer itself does the coding from the detail in the electronic record and the coder becomes more of an editor, validator, or monitor of the system.

Last summer, the AHIMA Foundation of Research and Education (FORE) undertook a fraud study for the Office of the National Coordinator for Health Information Technology (ONC) and the HHS OIG. The oversight committee was made up of fraud experts from health plans, providers, healthcare associations, and government including the Department of Justice and the HHS Inspector General's office. Among its "guiding principles" and recommendations the reports called for "standardized reference terminology and up to date classification systems that facilitate the automation of clinical coding are essential to the adoption of interoperable EHRs and the associated IT enabled healthcare fraud management programs." The reports from this study ("Report on the Use of Health Information Technology to Enhance and Expand Health Care Anti-Fraud Activities" and "Automated Coding Software: Development and Use to Enhance Anti-Fraud Activities") are posted on both the Office of the National Coordinator's Web Site and the AHIMA/FORE Web Site.

PHRs and Claims Data

In recent months we have also seen a significant increase in the importance of consumers having a personal health record (PHR). Educating consumers on the value of using a PHR is a high priority in my profession, and we welcome providers, health plans, and others who are looking to improve healthcare through the use of PHRs. However, even as we move to provide this data to our patients/consumers, another emerging trend is to build or sponsor PHRs that take their clinical data from the claim forms—namely, the ICD–9–CM and other classifications (CPT® in ambulatory claims) data.

I and many others in health information management and medical informatics are deeply concerned about this trend for all the reasons I have cited—the vagueness and limitations of today's claims data. If we begin to populate these PHRs with claims data based in ICD–9 and do not warn the owner and users of the limitations, we could have significant negative impact on the owner of the personal health records. In addition to the limitations of the ICD–9–CM coding system, the ICD–9–CM codes on claims are truncated, as noted, at 9 codes. This means the information is not only potentially vague, but also may not reflect clinical information that is important but has been truncated in the claims process. In addition, codes on claims often reflect coding that has been altered to meet the health plan or payers reimbursement instructions. Personally, I believe that it is unsafe to develop these PHRs without:

- Diagnostic and procedure detail that can only be provided in a contemporary classification;
- Industry agreement for consistency in coding so codes are not changed for reimbursement purposes; or
- A clear statement that the information in such records does not represent all the diagnoses or procedures that potentially were identified in any episode of care.

Example: How ICD–9–CM does not reflect modern medicine.

I wanted to share some examples of the coding problems we are experiencing with regard to its reflection of modern medicine. Two that recently were addressed at the March 2006 ICD–9–CM Coordination and Maintenance Meeting included non-Hodgkin's lymphoma and secondary diabetes mellitus

Non-Hodgkin's Lymphoma

There are more than 30 subtypes of non-Hodgkin's lymphoma. The request was to update the non-Hodgkin's lymphoma codes to allow for more current classification. This involves the creation of several new codes for specific types. Currently, "non-Hodgkin's lymphoma" is indexed to 202.8x (with the "x" referring to a fifth character for the specific site). However, there is no space for expansion in category 202. So, it has been proposed that category 200, which is currently limited to lymphosarcomas and reticulosarcomas, be expanded to also include several new codes for subtypes of non-Hodgkin's lymphoma. To maintain consistency with longitudinal data, non-Hodgkin's lymphoma, not further specified as to subtype, would continue to be classified to code 202.8x. This code includes lymphomas other than just non-Hodgkin's lymphoma. Due the limited codes left in the system, it is not being proposed that a code be created specifically for non-Hodgkin's lymphoma not further specified as to subtype.

So now, until we upgrade ICD–9–CM to ICD–10–CM, codes for non-Hodgkin's lymphoma subtypes will be distributed between two entirely different categories, with no unique code for non-Hodgkin's lymphoma not specified as to subtype. This will have a serious impact on data retrieval and,as I noted before, coding accuracy. Non-Hodgkin's lymphoma codes will not be grouped together, which means data analysts and coders could miss identifying all the related codes. The non-Hodgkin's lymphoma cases that are still classified to code 202.8x will not be able to be specifically identified as non-Hodgkin's lymphoma cases because this code includes other types of lymphomas as well. Data retrieval for lymphosarcoma and reticulosarcoma will also be affected because category 200 will no longer be limited to these conditions. This impacts not only physicians and hospitals, but also our cancer registries, researchers, and others. Meanwhile, ICD–10–CM has numerous specific codes for non-Hodgkin's lymphoma that are organized into appropriate categories.

Secondary Diabetes Mellitus

The diabetes classification in ICD–9–CM is also outdated—in ICD–10–CM, the diabetes codes reflect the American Diabetes Association's current clinical classification.

In ICD–10–CM, there are distinct categories of codes for diabetes mellitus due to underlying conditions and drug or chemical induced diabetes mellitus. In ICD–9–CM, these conditions are all classified to code 251.8—other specified disorders of pancreatic internal secretion. It has been proposed that a new category of codes be created in ICD–9–CM to capture secondary diabetes mellitus. However, in an effort to conserve codes, an attempt is being made to cover both diabetes mellitus due to an underlying condition and diabetes mellitus due to drugs or chemicals into a single category of codes. This will result in confusion and coding errors due to the differences in coding diseases that are due to an underlying condition and those caused by drugs. All the requested information is in the medical record(s), and it is much clearer from both a coding and data analysis perspective to distinguish drug-induced diseases from those caused by an underlying condition. However, but this cannot be done under ICD–9–CM.

There are many examples highlighting the differences between ICD–9–CM and the classifications originally designed in the 1990s (ICD–10–CM and ICD–10–PCS) and maintained for conversion that show the differences in detail and organization. I would invite you to contact the Centers for Disease Control and Prevention (CDC)-National Center for Health Statistics (NCHS—custodian of ICD–9–CM, volumes 1&2 and ICD–10–CM) and the Centers for Medicare and Medicaid Services (CMS—custodian of ICD–9–CM volume 3, and ICD–10–PCS) for a much more detailed look at the differences between the two generations of classification systems. You can also contact the American Hospital Association (AHA) and AHIMA who constitute the provider and professional organizations overseeing the coding guidelines for ICD–9–CM.

A few other examples where ICD–9–CM does not reflect modern medicine include:

• Myeloproliferative disorders and myelodysplastic syndrome—classified as neoplasms of uncertain behavior in ICD–9–CM, but now recognized as hematologic malignancies

• Many conditions are classified according to outdated thinking. Examples include neuromuscular disease, essential tremor, epilepsy, transverse myelitis, stroke.

• Alzheimer's disease codes in ICD–10–CM are more reflective of current medical knowledge.

Why is ICD–10 necessary to keep the U.S. in concert with the rest of the world?

It should be no surprise to the subcommittee that we live in a small world. In recent months, the media has reported numerous stories related to the avian flu outbreak and the potential for pandemic outbreaks in the U.S. as well. This has generated attention in Congress, the Administration, the states, and localities. Unfortunately, the U.S. would have difficulty in tracking a pandemic outbreak and comparing our data internationally.

Does the U.S. have a diagnosis code for avian flu? No.

Does the World Health Organization have such a code? Yes.

Does the U.S. have codes for West Nile Virus, SARs, or potential bioterrorism? We do now, but we didn't have them at the time of the U.S. outbreaks or for our first anthrax incidents when they occurred.

Why is the U.S. behind? Essentially because we are not on the same ICD-based system that most of the world is on, including all of the other industrial nations. They have converted to ICD–10 while we continue to linger and plod along with a system designed and implemented in the 1970's.

The ICD–10 codes are different than ICD–9–CM. Instead of five characters in version 9, version 10 has seven, and instead of being only numeric in version 9, version 10-based codes are alphanumeric. So, when a new disease is recognized by the WHO, the U.S. has to take the code and figure a way to renumber it and then put it in our coding system. As we discussed before, some of our chapters are out of codes. This is not an easy task and it is getting harder all the time.

Avian flu, SARs, and other diseases get a lot of press, but we must not forget that information must be transferred for research and public health purposes hundreds of times daily. When this exchange is between a U.S. public health department, the Centers for Disease and Prevention (CDC), or a research team and another ICD–10 country it means that someone must translate the codes. Because we have not moved to ICD–10 based classifications there has not been a lot of development of electronic translators or maps. What does this mean in today's environment? It means doing this by hand.

This problem grows because if it is ICD–10 information coming in to the U.S., the receiver has to map it to the vague ICD–9–CM codes. Obviously, some researchers choose to just work in ICD–10 and they can do so if they do not have to look at information contained in both classification systems. Yet doing business this way or using translators is not without a cost. I suspect the pharmaceutical companies, major researchers, health data organizations, and other healthcare companies doing business internationally can give you the economic impact that occurs because of these differences.

This is a good point to note that ICD–10–CM has been restructured to facilitate not only computer-assisted coding, but also to work hand-in-hand with electronic health records that will have a vocabulary base. The most common vocabulary is SNOMED–CT®, which is the designated vocabulary the federal government will use. This means that ICD–10 has now become the base system for future versions. Future versions may be expanded to reduce the differences between the U.S. clinical modifications and the international code as well as to work to smooth the interrelationship with other classifications such a functional status codes. The longer we remain on ICD–9–CM the longer we can not get the benefits of this classification, which has been designed to work with the standard EHR that Congress, the Administration, and many in the industry want to see in place.

U.S. Mortality Coding

The problem is not just between the U.S. and other countries. In 1999, the U.S. upgraded its mortality reporting system to use ICD–10. This was done in part because of our international agreements (through the CDC's NCHS) and the need to look at mortality on an international basis. So today, in 2006, each of the U.S. states, district, and territories report mortality data monthly ICD–10 on a monthly basis. This leads to the question of whether we can easily look at U.S. mortality data versus our morbidity data. The obvious answer is no, not without the same mapping or conversion process that we must use for international data.

Crosswalks

Crosswalks or mapping are terms we use to describe the connections, or paths, between classifications and vocabularies. There are several needs for a mapping associated with ICD–9–CM and ICD–10–CM or ICD–10–PCS. We have already discussed the need to map between data from the U.S. and other countries or between

our current morbidity and mortality systems. Such a map is also needed for the purpose of maintaining a longitudinal patient record to ensure that data in ICD–9–CM and one of the ICD–10 classifications can be obtained for a variety of reasons including clinical care, research, fraud monitoring and so forth. A third reason for a map might be to permit a healthcare plan or payer to accept claims with ICD–10–CM or PCS data, but map it back to ICD–9–CM so that the claim can be adjudicated on an older system that was not converted.

This last use is a practice used in Canada to alleviate some of the implementation issues during that country's conversion. It is not a recommended practice because when you map back from ICD–10 to ICD–9, you lose most of the detail I have spoken of and consequently the initial benefits and savings that might come from simpler claims administration. This is not beneficial for either the plan or the provider. A similar use of this process is the function of fraud monitoring. For fraud monitoring, a plan might carry a three-year rolling set of claims data in order to detect fraud. To do this would require a three year period where you would keep data in ICD–9–CM, but once the three years is completed, you would have built a 3-year history in ICD–10 classifications. Technically, you could also map the ICD–9–CM data to ICD–10. Again, these are not the optimal solutions, but they are feasible and they do allow for the need to work through an initial implementation period.

I must indicate that both of these ICD–10 classifications have been maintained since they were originated. The update for ICD–10–PCS was just announced in the *Federal Register,* and the update for ICD–10–CM is due in June. The mapping between ICD–9–CM and ICD–10–CM will also be forthcoming shortly from the CDC–NCHS.

I noted that mapping occurs between classifications and vocabularies and that vocabularies would serve to be the data base for standard electronic health records. Therefore, mapping must occur between ICD–10–CM and SNOMED–CT and ICD–10–PCS and SNOMED–CT. Mapping has been completed and verified under the National Institute for Health's (NIH) National Library of Medicine (NLM). At a February 2006 meeting of the NCVHS, the NLM did announce that it is ready and waiting to map between the ICD–10 classifications and SNOMED–CT, but it cannot do so until the two classifications are officially adopted by the HHS.

Conversion Costs

The question of conversion costs often arises as we discuss the upgrading of ICD–9–CM. In 2003 the NCVHS asked this question of the Rand Corporation and through Rand's report was told that costs for the U.S. (in 2003) were in the range of $425 million to $1.1 billion. Rand also noted that the anticipated benefits would be between $700 million and $7.7 million because of all the advantages of detailed information—many that I have mentioned before.

Significant losses in coding productivity and accuracy are resulting from the use of ICD–9–CM terminology that is not consistent with current medical practice. For example, coding professionals must often consult physicians for clarification regarding the appropriate code. Time is wasted when coding professionals have to try to determine the "best" code when none of the options seems appropriate. Often, the wrong code is selected due to the inability to determine the best ambiguous code or conflicts between ICD–9–CM terminology and terminology used in the record. Many of the coding questions that arise stem from the ambiguity and inconsistency of ICD–9–CM and the outdated terminology that is not reflected in current medical record documentation. As the obsolescence of ICD–9–CM continues to increase, these problems will grow even more.

Increased costs are also incurred due to the extended time required to code cases where more and more disparate conditions and procedures are classified to the same code.

As long as we continue to use ICD–9–CM, the coding process will be heavily labor-intensive—i.e., manual coding process. The use of computer-assisted coding tools is limited with ICD–9–CM due to the code ambiguity, lack of precision, and inconsistent terminology and definitions. No matter how sophisticated electronic applications become, their use in the coding process will be limited as long as ICD–9–CM is in use. Once ICD–10 is implemented, the use of electronic coding tools will grow dramatically and these applications will become increasingly sophisticated—greatly facilitating the coding process and reducing the manual labor involved.

Essentially the systems' change created by ICD–9–CM being upgraded to the ICD–10 classification is one of an expanded field. The other change is moving this larger field from numeric to alpha-numeric. So, the systems that have to have the field changed, technically, are any software that has the ICD–9–CM code, and any electronic data base that contains ICD–9–CM codes. Currently, most of the systems that have extensive coding in software or in the data base are in hospitals, health

plans, and reporting and research organizations. This is not to say that they do not exist in clinic, physician practices, and ancillary services. But, as you know, there is a substantial healthcare provider population that is still essentially paper-oriented, and even many of the organizations I mentioned may have only one or two systems, not a full EHR or administrative system. While software vendors will make the change to the software (and many international firms have experience with ICD–10), database upgrades will involve both the owners and vendors.

The longer we wait to make the upgrade to ICD–9–CM, the more expensive such a conversion will be, if for no other reason than the government and healthcare industry are pushing various entities into purchasing electronic health programs, records, reporting mechanisms, and the like. We have set goals and projects, even in Congress, to get providers to send information electronically. Healthcare entities who electronically expand their systems, purchase replacement systems, and so forth will have to make the ICD–9–CM upgrade to ICD–10 as a retrofit. If you have purchased the software or are beginning to build the database you will have to retrofit your system. Anyone who has renovated a house or office knows the renovation is often more costly than building in the first place. The same occurs for electronic systems.

The need to "retrofit" ICD–10–CM and ICD–10–PCS into a greater number of system applications, declines in coding productivity and accuracy due to difficulties in trying to use a failing coding system, and the implementation of "band-aid" approaches to keep ICD–9–CM afloat and attempt to meet healthcare data demands as much as possible. For example, increasingly, CMS has been forced, due to space constraints in the ICD–9–CM procedural coding system, to disrupt the hierarchical structure by starting to use available codes in unrelated code series, with the result being an unstructured, haphazard coding system. A hierarchical structure assists in defining coding concepts by placing them into organized, distinct groupings. Disruption of this hierarchical structure causes the complexity of using the system and mining coded data to increase dramatically and leads to declines in coding accuracy. Additionally, the U.S. will continue to incur the costs of maintaining ICD–10–CM/PCS as well as ICD–9–CM for all of the years between now and implementation.

I must point out the obvious: the standards for ICD–10–CM and ICD–10–PCS are available now. The standards for the transactions that must also occur, the conversion to ASC X12 Version 5010 and the NCPDP upgrades are also known. If products (systems and software) were built from this point forward that could handle both code sets, then buyers would not have to retrofit later. It is not unusual to buy a product that is ready for a future change such as the high definition televisions that are sold in anticipation. I understand, however, that vendors are reluctant to include the ICD–10 classifications in existing and near future products. It costs money to make such conversions in systems, but they have heard rumors of upgrading ICD–9–CM since the mid-1990s. So, why should they run the expense? The vendors want a formalized notification so they can move forward. At this stage, the notification must come from the federal government. It is important to express that HR 4157 explicitly addresses the notification issue by calling for a "notice of intent" to be sent out by the Secretary within 30 days of the passage of this provision. This is absolutely necessary.

Delay

Last summer, my professional association, AHIMA, issued a statement calling for the implementation of the ICD–10 classifications by October 2008. After your hearing on this issue last July, it became apparent that such an implementation could not occur until October of 2009, and only if the bill is passed. Without the bill, under HIPAA, the earliest conversion could occur would be 2011 or 2012.

I have already pointed out a number of examples of what happens when we have no codes in our diagnoses area, or if we have no sequential codes in the procedures area. Our data becomes more vague and more suspect. There will be more and more calls for additional information from the medical record. Quality data, injury data, all of this will be suspect because procedure and diagnoses codes are taken off the claim, and we will not have the detail to provide an ample picture of the patient's health without considerable manual efforts. Congress continues to call for better payment systems, report cards, and other measures of care and healthcare value, but the cost of providing such data with a classification system that does not represent 21st century medicine will increase rapidly or no data will be provided because providers will not have the money to provide data outside of the existing claims system.

The United States is the last hold-out in the industrial world to convert to an ICD–10 based system. What is the cost to research as we go through the manual efforts I have described year after year? Perhaps we could use maps, but we are

mapping between much greater detail from other countries, and a rather vague and somewhat violated system of codes. How long does our public health system have to hope that we have codes to describe and track international outbreaks? How easily will we be able to share biosurveillance data?

We are currently in the midst of a massive effort to ensure standard electronic health records and to provide a nationwide health information network. Certainly our electronic records will improve clinical care and to rapidly transfer records across the country will be great. But, what about all the other data transmitted through the network—the secondary data? If we cannot clean up our secondary data by upgrading our ICD–9–CM system, then it will be like sending polluted water through a new pipe system.

I see a day, in 2010, when my coders can code accurately with ICD–10 and not have to guess at the code, or merge it into a catch-all code—a day when the ICD codes truly represent the information our clinicians have entered into the record.

I see a day when a standard electronic health record can provide the initial ICD–10 coding information because of a standard map between its SNOMED–CT base and our ICD system, and coders will become validators of the process and not the process itself.

I see a day when my organization can send a claim and have it processed because all the information needed is in the ICD–10 codes and very few claims will result in a request for more information. And, because this claim's information is so valuable, it can be used in quality and injury monitoring programs and where healthcare can be reimburse, on the basis of outcomes and quality.

I see a day when public health and researchers can trade and use data internationally, in the form of ICD–10 based codes for monitoring and for instructions when an outbreak occurs.

Few of us are using the electronic standards for personal computers and similar devices we bought 10 years ago, let alone 30 years ago. Why do some feel comfortable doing so with our data standards?

HR 4157 calls for a review of priorities. Should the provider and payer identifiers be put aside to get better clinical data? We are not running out of identifiers at present and current identification numbers work in our systems. Should the potential for a HIPAA claims attachment that will only affect 2 percent (according to the National Uniform Billing Committee) of claims be delayed until we implement a classification system that can eliminate the need for attachments for many more claims?

These are questions that must be answered, and I congratulate Chairman Johnson and the subcommittee for providing leadership on this issue. I would be pleased to answer any questions you might have and I also point you to my professional association, the American Health Information Management Association, for a response to any further questions. Thank you.

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Chairman JOHNSON. Thank you very much, and I thank the panel.

Ms. Bryant, it has been very interesting to me that you have actually implemented ICD–10, trained for ICD–10, and actually know quite a lot about what kind of challenge that will pose for a system.

First of all, I want to ask you whether or not you think it is possible to pilot ICD–10, and, secondly, I want the other panelists to comment on why we might need to delay or why we might need to accelerate.

You do in your testimony make an overwhelming case for the need for a better coding system as we move to an era where quality has to be judged and has to be associated with payment, whether it is hospitals, doctors, nursing homes, or anything else. So, the fu-

ture is upon us in our need to be able to evaluate quality. The CASM and Institute of Medicine studies showed what a terrible job we are doing for lots of money. So, I just want to pose that question to you, and then I want to give Mr. Henry, Mr. Smith, and if Dr. Kizer is interested, any comments from them.

You have to get closer or make sure your microphone is on. Did you turn it off?

Ms. BRYANT. Thank you. To answer the first part of your question about beta testing or trialing this, you may recall there was a field test project that was done in ICD–10 by the American Hospital Association and the American Health Information Management Association, which I have available if anyone on the panel wants to look at it, and there was a testing done of ICD–10.

I have taught coders to use this, and one of the interesting aspects of the teaching was the overwhelming response to the change. Most people are very pushback with change, and I have had coding professionals, 30-year-old individuals who have been doing this for years and years, not wanting change, say to me, "This is a good system. We needed this years ago. Where has it been? How come we don't have it?" Because the medical records do have the documentation to support the codes, we can provide good data across the Nation, and it can be used in multiple formats.

So, I strongly support that we would be able to implement within a shorter period of time than some people are recommending, our colleagues are recommending, and we could roll this out within that timeframe start October of 2009.

Chairman JOHNSON. You mentioned the 3-year timeframe.

Ms. BRYANT. Yes.

Chairman JOHNSON. So, you are saying the 3-year timeframe would start in 2009 or end in 2009?

Ms. BRYANT. It would end in 2009. We would go live October of 2009.

Chairman JOHNSON. Okay. Any comments? Mr. Smith.

Mr. SMITH. Yes, thank you. We would encourage a broad, full, end-to-end pilot testing be undertaken to prove this out using not just the health care coding in a hospital but actually take it through the entire coding system of hospitals and physicians, through their clinical systems, through the practice management systems, utilizing the ANSI 5010 formats off to the health payors and have all that full pilot testing be completed before we would step into the full exposure and learn from those pilot testings on a true end-to-end test.

Chairman JOHNSON. While the 5010—just to make the record clear, the 5010 is certainly scheduled to be implemented. The proposal does not involve implementing ICD–10 in the doctor's offices. That was JCPT code covered.

Mr. SMITH. The physicians do have to be involved in that because in order for them to do their billings of their health care transactions, they must report a diagnosis, and that diagnosis would be moving to the ICD–10 format, even though they are still using the Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System for the procedure codings. They would have to relearn and be trained in how to report that diagnosis coding, and that we believe is a pretty significant training ef-

fort for the physicians to have to go through, as well as into their electronic health records and their practice management systems, which do not currently recognize the coding structure of the ICD–10.

Chairman JOHNSON. That is true. They still do have to code, and one of the questions is the question Dr. Kizer raised. You have got to give notice if you are going to make change and how many changes do you need to make at once rather than making a big change and then a big change, and then a big change and a big change.

Ms. Bryant, did you have any comment on this issue of the doctor's office involvement in the model that you have tried?

Ms. BRYANT. Right, I would like to comment on that, and the data that was done back with American Heart Association and American Health Information Management Association did include physician office, a smaller portion of that. In addition, we have looked at what—a physician's office typically uses a billing form, uses—the terminology is called a "super bill." It lists procedure CPT codes for the services of the visit, and then another part of that is the diagnosis codes. Not altering but adding a column to the one form of the crosswalk from a standard practicing physician's office, it is easily achieved and was done in 4 hours to put in place and be used. These are updated annually, as they should be from a compliance perspective, but it is not that time-consuming. My educational experience with physicians—and physician office staff is, again, very eager to get a better coding system. They recognize the frailty of ICD–9 and that it has problems.

Chairman JOHNSON. Mr. Henry, is Partners thinking about any of this?

Mr. HENRY. I have to say that Partners does not have an official position with respect to ICD–10. In connection with my coming here today, I did talk to a few of my colleagues who said that it is their view that, since we are eventually going to have to move to an ICD–10 format, probably better sooner than later.

Chairman JOHNSON. Dr. Kizer?

Dr. KIZER. Again, not taking any formal position, I would certainly agree with Ms. Bryant that the ICD–10 offers many advantages over the current system, but recognizing your interest in quality, there is one particular area that needs a solution. As you know, the National Quality Forum has achieved consensus on what are known as serious reportable events, 27 egregious medical events that simply should never happen in health care. These have been legislated as mandatorily reportable in half a dozen States. Many other States are also considering this requirement, but ICD–10 would not allow coding for about half of those or more. Relatively few of them would be coded under ICD–10. It would be nice if one could find a solution to that type of problem.

Chairman JOHNSON. That is interesting. Did you want to comment, Ms. Bryant?

Ms. BRYANT. Yes, thank you. Certainly all the current formats with ICD–9 will have their crosswalk. Those are developed already. The crosswalk back from 10 to 9 is in process, should be out soon, but that is primarily the issue. The risk services community that I have worked with in hospitals, in my particular hospitals I

trained them on ICD–9 to capture diagnosis-related risk areas—accidents, punctures, that sort of thing. They are eager to see specificity in the data because we cannot capture it in 9 as it is now. They would like to see that sooner than later to save costs and save lives.

Chairman JOHNSON. Thank you very much.

Mr. Stark.

Mr. STARK. Well, Madam Chair, this is a fascinating panel. If Mr. Smith, Dr. Kizer, and Mr. Henry will permit me the Tinker-to-Evers-to-Chance play here, we are going to wrap this all up.

Mr. Smith, you said in your testimony that health plans are generally the only stakeholder in the health care system that collects information from almost all providers that their members visit and, therefore, the only stakeholder that can give a physician a cross-provider view of a patient's history. Do you stand by that?

Mr. SMITH. That is a general statement, yes.

Mr. STARK. Who is the biggest payor?

Mr. SMITH. Medicare.

Mr. STARK. You got it. So, we will stick with you there. Then—and you just led right into this. This is great. Then you said, finally, common, non-proprietary standards are essential, allowing various vendors to either dictate their preferred proprietary data formats or protocols or to become intermediaries or clearing houses would hold other stakeholders hostage. Right?

Mr. SMITH. That is correct.

Mr. STARK. You like that, Dr. Kizer? Does he just feed right into what you are saying?

Dr. KIZER. That sounds interesting.

Mr. STARK. Then I am going to solve Mr. Henry's problem. As Dr. Kizer just suggested, although we are going to turn it on its head, that we have a differential rate. If to get this all together—because Mr. Smith does not know it, but this Committee wrote the design for the way he now reimburses physicians, didn't we? Blue Cross came on—after we did physician reimbursement, most of the Blues throughout the country adopted it.

If, in fact, the differential rate that you talked about was enough, short-term, 5, 10 years, enough for Mr. Henry's community to amortize the costs and the training, he will get enough money through—or his doctors and offices will get enough money to be able to participate in the system, and I think then your problem goes away, doesn't it, Mr. Henry?

Mr. HENRY. Perhaps in the long term, but not in the short term.

Mr. STARK. Well, in the short term, if we pay in enough, assuming that we are front-loading it, because the training and the equipment comes up front and from then on it is more updating and upcoding—let me put it this way: It is possible to resolve your problem that way, is it not?

Mr. HENRY. Oh, yes, I don't think——

Mr. STARK. Eliminating then any chance of one hospital competing with another to buy them a fancier computer to get them. So, I think if what I am hearing from you all about the payors being the people who can basically through a differential rate or the "hammer," if that is not a bad word, a differential rate for lack of participation, an open-source system which Dr. Kizer has so elo-

quently defined for us here, a way to pay directly to the people who are going to use the system, we have wrapped it all up. Okay?

Dr. Henry, Mr. Henry, you came all the way from Boston just to get that resolved, and my best wishes to—is Massachusetts General in your——

Mr. HENRY. Yes.

Mr. STARK. Who is head of surgery?

Mr. HENRY. I am sorry?

Mr. STARK. Who is head of surgery at Massachusetts General?

Mr. HENRY. At Massachusetts General?

Mr. STARK. You don't remember, okay.

Mr. HENRY. Now you are going to embarrass me.

Mr. STARK. Thank you very much—yes, please, Mr. Smith.

Mr. SMITH. I would like to comment. I think in terms of the strategy you have laid out, it is good. I think we also need to consider, though, a number of the other activities that are also in play at the same time which are contending particularly for resources in all three of the constituencies of the government, the private sector, and providers and health plans, and the number of the things that need to go on and to work in an overall aggregate game plan to do that in a logical, sequential fashion to make that happen. That would be the——

Mr. STARK. My only reason for saying that, Mr. Smith, is that, as I said, we have had studies since 1996; we are going to have more studies. At some point we have got to just say, guys, let's do it. Then some of Mr. Henry's physicians may not fit in well. The Blues in Arkansas may get a little strained to get into a system that might be government, and we will have to make changes. We know that, but at least everybody is in then. We are in a system which we can then adjust. You had that problem with the Veterans Administration, didn't you, Dr. Kizer? You started it, and I am sure that the Livermore Hospital did not get a lot, the Palo Alto Hospital and——

Dr. KIZER. That is certainly a fair statement. There are two things I would just raise. One is indeed when we were trying to make the decision on moving forward with VistA, or I should say when I made that decision, there was a lot of resistance and there was a lot of talk about, well, we cannot do this in the time that you have said, and there was, in that case, an executive decision that, effective January 1, 1996, we would move forward. Setting a firm timeline and then holding the organization to it did result in the successful implementation of the largest deployment of electronic record in the world ever.

Mr. STARK. Well, we are counting on the chairwoman to beat you, and when she mandates that we get it done in a couple of years, we are going to go right past the VA like they were running backward. Okay?

Dr. KIZER. It would be perhaps of interest—and I do not mean to put Ms. Bryant on the spot here, but it is my understanding, if I read the newspapers correctly, that Catholic Healthcare West has made a corporate decision to only go with open-source solutions, and I don't know if she might want to comment on that.

Ms. BRYANT. I don't have a comment on that.

Mr. STARK. Thanks, Madam Chair.

Chairman JOHNSON. Thank you. I would like to note that the President set a timeline and said by 2010 America is going to have an interoperable health information system, and that is why we have seen so much activity. That is why we are seeing so many advances. That is why this bill is here, to lay the predicate, what has to be a part of that system in a number of different areas, and I just do not want that to go unnoticed.

The other thing is, it is interesting that the Department of Defense did not adopt VistA. I do not have time to pursue that right now because I am going to yield to my colleague——

Mr. STARK. Can I put 2010 in the bill, Madam Chair?

Chairman JOHNSON. Pardon?

Mr. STARK. Can I put 2010 in the bill?

Chairman JOHNSON. We are going to get there earlier, so we do not want to do that.

Mr. McCrery?

Mr. MCCRERY. It seems to me that if we want to create a system which is the most flexible, the most able to adapt to new technology, to new trends in medicine, or whatever, we need to be very careful about imposing a system or even suggesting a particular system, and that is why I am a little nervous about just saying in order to do this thing quickly and get everybody on board, let's adopt the VA system and go with it. We need interoperability, but interoperability, if we do it right, can allow a number of from vendors, whatever, to come in and be innovative and develop new systems that could be better than the system that Mr. Stark is suggesting that we basically impose upon providers right now.

Do you all disagree with that? Mr. Smith, you can go first.

Mr. SMITH. Thank you. I fully support your position on that. Go back to our Advanced Health Information Network. We had interoperability, clinical, administrative, and financial. We allowed any of the providers to leverage any of the back-room IT operations that the providers or other participants had, and had to form the interfaces into the common standards for the interoperability, and that worked. We plugged it together, and as I say, it was operational. That, all we had to do is work toward those standard interface points, and the back-room operations of all those systems remained in place.

Mr. MCCRERY. Dr. Kizer?

Dr. KIZER. Mr. McCrery, I would hope you wouldn't take my comments as suggesting that one should mandate VistA. What I am merely suggesting is that this public investment that has already been made be made more available to the commercial sector through a mechanism that was outlined in my written testimony. VistA is currently being used in the commercial sector. It is being used in hospitals and clinics in the private sector successfully. There are ways that its availability could be speeded up for those who chose to go that way. There are ways that those benefits that have been developed in the private sector could be fed back into the government.

What I am outlining is merely a mechanism to allow this to be an option that is more readily available in which it would develop the interfaces and other things with other systems.

Mr. MCCRERY. Okay. Good.

Mr. Henry?

Mr. HENRY. If I can just comment, I think that while it would be ideal if we had a single government system that was paid for by the government, the reality is that at Partners we are actually dealing with a homegrown system. We are also allowing our physicians to use commercial systems. In order for those two to talk to each other, there has to be interoperability. The reason that we are still advocating for some kind of a fraud and abuse exception along these lines, however, is that even though you have software that may be free, you still have the cost of conversion; you have the cost of training; you have the cost of supporting with a help desk. Those are all costs that physicians at this point in time are not able to bear.

Mr. MCCRERY. You have in your system both physicians who are employees of your system and physicians who are not employees. Is that correct?

Mr. HENRY. That is correct.

Mr. MCCRERY. Under the current Stark laws and anti-kickback laws, can you treat both your physician employees and your non-employee physicians the same with respect to IT?

Mr. HENRY. We cannot. We——

Mr. MCCRERY. Explain the difference.

Mr. HENRY. We have told our employed physicians that our homegrown system is the system that you are going to use. We have put it on all their computers, and since the computers are our computers, they are pretty much forced to use it unless they are technically challenged, which some of them are.

With respect to the non-employed physicians, we cannot give that software away, nor can we pay for it and any other option that they would choose to buy because that would be considered remuneration. Since those physicians are in a position to refer to us, that would violate a very black-and-white Stark law.

So, my CEO, when he found out about this, as he was putting together his signature initiatives concept, was very concerned that we were in pay-for-performance contracts that obligated us to reach certain goals that we could only reach by using through half of our physicians. We had to cajole, convince the rest of the non-employed physician community to pay for these on their own, because if we were to subsidize them, we would be in hot water with the Stark laws and the anti-kickback fraud and abuse laws.

Mr. MCCRERY. So, you would like some safe harbor which would allow you to assist those non-employed providers with technology?

Mr. HENRY. That is correct.

Mr. MCCRERY. How do you counter the expressed fear of some that if you were to do that, if you were to assist your non-employee providers with this technology and training and so forth, that it would create a captive referral system, for example, that you would just make them refer all their patients to you because they are indebted to you?

Mr. HENRY. Well, the reality in our system is that we have a network that spans a pretty wide geographic area, and close to 60 percent of the physicians, community-based physicians in our network refer to other hospitals outside of our system. This network

is really about providing care for the patients of the insurance companies that contract with that network. So, from our perspective, it is important to keep that network intact, and if we were to tell those physicians that in order to use our system they have got to refer to us, they wouldn't use it. Or if we were to tell them that our homegrown system was not interoperable with whatever system any of their other hospitals might be using, they would not adopt it.

The other reality is that almost all the Partners hospitals are full. We have no incentive to increase the care at our system.

Finally, I should say that we are incentivized by our payer contracts to provide what we call the right care at the right place at the right time, which means to be more efficient. If a patient is more effectively cared for in a smaller community hospital at a lower cost, we get rewarded for that. So, we are simply asking for our ability to help physicians put together their own electronic medical record because we want to provide better care at lower cost, not because we need the referrals.

Mr. MCCRERY. Well, what you have just outlined are basically reasons that the market would prevent you from controlling referrals from these physicians. I happen to think you are correct, and I have no problem with that, but there are some among us who do not really trust the market to protect consumers from that kind of activity. So, are there any precautions that you might build into the safe harbor that would tend to mitigate that possibility of creating a captive referral system?

Mr. HENRY. Sure. Well, first of all, any support along these lines must not be able to take into account any kind of volume of referrals.

Secondly, as a public policy matter, as any hospital should be looking to help with support to any local physician community, they ought to be looking at other criteria that relate to that physician's ability and commitment to deal with certain quality measures, their expertise in using electronic medical records and digital communications generally.

We think that if you tie the physicians' readiness to adopt the quality measures and use the software that is being provided, and prohibit any of those considerations to relate to the volume or value of referrals, that those should be criteria that would go a long way to making sure that the safe harbor works.

Mr. MCCRERY. Thank you very much.

Chairman JOHNSON. Thank you very much. I appreciate the panel's input.

Mr. Henry, I did not get a chance to do it when we were questioning, but I appreciate very much the specificity of your concerns in your testimony with the OIG's proposal, and I did talk with him about it beforehand. It does not do any good to have an exemption that is as narrow either from the system's view or from, in a sense, the entity view as his thinking appeared to be in the opening effort. I think he had looked at your testimony and he is very serious about the public input that he has received, and we will see where that goes.

I think this issue about what is open source and what is competitive is a very interesting and important one. I do think that inno-

vation is what brought us to this point, and the government has never been an innovator. In fact, the big problem with the government is that we finally do catch on. By the time we legislate, we are behind the wheel, and then we do not pay attention for another 10 years. So, you get very sort of modern-thinking Members like Mr. Emanuel frustrated as can be, and I do not want that to happen here.

So, nothing anyone is doing to my knowledge prevents a movement to open source, but whether the government should mandate that, I think that is a question that we need to look at in much greater depth than we have, and I thank you, Dr. Kizer, for bringing it up. I thank each one of your for you input and testimony and for the enormous amount of experience you have brought to the table today.

Thank you. The hearing is adjourned.

[Whereupon, at 4:30 p.m., the hearing was adjourned.]

[Submissions for the record follow:]

Statement of the American Clinical Laboratory Association

The American Clinical Laboratory Association (ACLA) representing national, regional, and local laboratories appreciates the opportunity to provide comment on activities that will accelerate the widespread adoption of the electronic health record. ACLA members have an extensive history of providing the nation's hospitals and physicians with leading-edge health information technology (IT) streamlining laboratory test requisition and speeding the delivery of test results.

The ACLA supports the Health Information Technology Promotion Act of 2005 (HR 4157) which proposes several needed improvements to facilitate the diffusion of health IT throughout the United States. These changes will help promote better outcomes for patients. Among the improvements are new Anti-kickback Safe Harbors and Stark Law exceptions; a study of, and subsequent authority to preempt some state privacy laws; and the replacement of ICD–9 diagnosis codes with ICD–10 codes.

Laboratories play a critical role in healthcare delivery by allowing for the rapid and timely utilization of health information by providers. Laboratories and the resultant medical information constitute up to 60% of the medical record. Diagnostic tests comprise only 1.6% of Medicare costs, but they influence a much larger portion (as much as 60–70%) of clinical decision-making that improves care and decreases cost. Virtually every health care community (i.e. Regional Health Information Organizations or RHIOs) that is trying to develop an electronic health information infrastructure is looking to incorporate laboratory data *first*. A recent nationwide survey by the eHealth Initiative found that, of those who have electronic health information exchange efforts under way, 60% plan to exchange laboratory information within six months to support quality, safety and efficiency goals. In a survey of hospitals, the number one IT function in the majority of hospitals today is the electronic order entry and review of results for diagnostic services.

The reach of laboratories into physician offices and hospitals vis-à-vis the provision of this hardware and software has served as a catalyst' in the evolution of health IT. For example, Quest Diagnostics Incorporated, a member of ACLA, has business relationships with approximately half of the physicians and hospitals in the U.S. Quest Diagnostics Incorporated receives 40% of orders and sends 60% of its results via the internet. Similar means of laboratory connectivity are offered by other ACLA's other members.

The federal government, quality organizations, the Medicare Payment Advisory Commission (MedPAC) and others recognize that laboratory data are the essential building block for assessing quality care and will have a critical role in pay-for-quality initiatives. Laboratories can and have been used to measure a provider's performance as a critical component of health care delivery; however, this contribution cannot be realized without incurring additional cost that must be recognized and reimbursed. In a detailed study of practice and laboratory connectivity, the eHealth Initiative recently recommended incentives that could be provided for including electronic laboratory data as part of pay-for-performance reporting. One example from the report would be to provide short term incentives, based on the volume of laboratory messages processed, up to a monthly dollar limit per clinician that would en-

courage implementation of interfaces. Incentives such as these can be an important driver of adoption of new technologies. By providing incentives encouraging the transmission of laboratory test requisition and results reporting, the healthcare system will actually save money through reductions in duplicative testing, better coordinated care and decreases in morbidity and mortality.

Because of the value that laboratories convey in the data they transmit, they have pioneered the provision of secure, streamlined IT solutions to order and transmit laboratory tests. This is a critically important and highly valued function. So important that since 1995 laboratories have had a limited exception under the Stark Law to provide "items, devices, or supplies that are used solely to . . . order or communicate the results of tests or procedures for such entity."[1] This is a fundamental capability for laboratories to render services to providers and a critically important function that must be maintained. Clinicians place a high value on being able to order laboratory services and receive laboratory results electronically because it improves legibility, decreases error rates, produces more timely results (including STAT testing), and allows the monitoring of redundant or duplicative testing. The result is improved clinical outcomes, and improved clinical care efficiency with the long-term benefit of reduced healthcare costs.

ACLA recognizes that physicians, hospitals and other providers routinely cite the fear of legal action/debarment from Medicare as one of the biggest deterrents towards adoption of health IT. Accordingly, HR 4157 establishes a new exemption for the provision of health IT and related training. ACLA believes this legislative proposal, if enacted, would help to address some of these concerns and prompt further adoption of the health IT; however, ACLA believes such an exemption should be crafted carefully to diffuse the technology while guarding against abuses. By doing so, providers will continue to compete on the services they are providing and not, for instance, the size of a monitor. However, in any law or regulation laboratories *must* be among those entities permitted to offer these items or services because of the critical role laboratories have, and continue to play in facilitating health IT adoption in the health care community. ACLA was particularly perplexed with HHS' Office of the Inspector General's recent notice on the establishment of new Stark Law exceptions and Anti-Kickback Safe Harbors which proposes to exclude laboratories from the newly created exemptions.

ACLA also supports the legislation's federal preemption of state laws that contradict the Stark Law exceptions and Anti-Kickback Safe Harbors established under the bill. Today, there are several states whose Stark' laws are complicated and have different requirements than the federal law. Similar to the privacy issue, the problem is not just that these state laws are more stringent, but that there are many different standards. The differences in these state laws fall into several categories, e.g. the scope of the exceptions to the prohibition or the scope of what is considered a designated health service.' By creating a federal preemption, Congress can help address the fear and confusion many providers continue to have as they contemplate adoption of various health IT solutions.

Another needed change that HR 4157 addresses is the need for federal preemption of state laws related to the security and confidentiality of health information. HR 4157 requires a study of: 1) the degree to which laws vary among the states; 2) between state laws and HIPAA; 3) how such variations adversely impact confidentiality and the electronic exchange of health information. Upon enactment, Congress will have three years to pass legislation establishing uniform federal standards and preempting state laws with regard to confidentiality and privacy. If not, then the Secretary of HHS is permitted to adopt regulations based on the results of the study.

ACLA supports this provision because the patchwork of state privacy laws is an impediment to health information exchange. For example, LabCorp, a large national laboratory, has been invited to participate in two of the eight regional Medicare Health Support pilot programs (previously known as the Chronic Care Improvement Program) authorized by section 721 of the Medicare Modernization Act. LabCorp has been invited to participate in an effort with CIGNA HealthCare in Georgia as well as a program operating in central Florida being operated by Green Ribbon Health, LLC. These entities will offer self-care guidance and support to chronically ill Medicare beneficiaries to help them manage their health, adhere to their physicians' plan of care, and ensure that they seek the medical care and Medicare-covered benefits that they need. LabCorp's role in the pilot programs would be to transmit laboratory data to CIGNA HealthCare and Green Ribbon Health for those beneficiaries who voluntarily participate in the program. This information would then

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[1] 42 USC 1395nn(h)(1)(C)

be used to help monitor the conditions of participants and ultimately, improve their outcomes.

Unfortunately, despite the well-intended efforts of these programs, more restrictive state laws in Florida and Georgia governing the release of lab results have prevented LabCorp from transmitting these important results to Green Ribbon Health or CIGNA HealthCare until its concerns about the application of those laws to these requests have been addressed. More specifically, the Florida and Georgia laws preclude providing test results to anyone other than the ordering physician or provider (or to a person specifically authorized by the ordering physician).

HR 4157 also addresses the needed replacement of the International Classification of Diseases, 9th edition, Clinical Modification (ICD–9–CM) diagnosis and procedure billing codes with ICD–10–CM/PCS codes. ICD diagnosis codes are used by inpatient and outpatient providers for billing and reimbursement. Under the Medicare program, laboratories are paid by including ICD–9 codes on their claims to provide medical necessity. These ICD–9 codes are provided by the physician to the laboratory and are subsequently attached to a claim and submitted to CMS. Today, as many laboratories will attest, problems persist with physicians not providing the appropriate ICD–9 codes in order for laboratories to get paid. Currently, ICD–9 provides approximately 13,000 diagnosis codes. Take into account that ICD–10 provides 120,000 diagnosis codes, thus one can see the need for an extended phase in of the new system.

ACLA recommends that the implementation period for the transition to ICD–10 be changed from a two-year phase in period to a five-year period. Doing so would provide adequate time to reprogram all health care providers' and payers' computer systems to accommodate the new, longer ICD–10 codes. In addition, considerable time and expense will also have to be spent on client education and testing of the new systems. During this transition period' it should be permissible for providers to bill using either the ICD–9 or ICD–10 standards.

The following examples demonstrate the increased coding complexity posed by switching from ICD–9 to ICD–10. There are currently nine ICD–9 codes that can be selected for classifying a patient with tuberculosis, based on the location and specific type of infection. ICD–10 expands the number of codes to 39. Similarly, there are seven classification codes for thyroid related disease in ICD–9. ICD–10 expands the number of codes to 44. This significant expansion in the number of codes will require reprogramming of provider and payer systems, physician and lab coder education, and general interoperability issues that need to be resolved to allow for a smooth transition from ICD–9 to ICD–10.

ACLA supports the Health Information Technology Promotion Act's new Anti-kickback Safe Harbors and Stark Law exceptions, the bill's proposed preemption of some state privacy laws, and a replacement of the ICD–9 with ICD–10 with a five-year transition period.

In summary, it has been said that every effort in the health care public policy arena aims to improve three different aspects of health care: better, faster, and cheaper. Few reforms meet all three objectives. Health IT does meet all of these objectives. It will make health care better by improving outcomes; faster, by facilitating not only the delivery of information but the coordination of care; and cheaper, by reducing the costs of doing business, be it a reduction in duplicative testing or by saving precious time previously spent on data entry.

Madame Chairman, thank you for the opportunity to share ACLA's perspective on ways to promote electronic health records and a smarter health information system. We are ready to work with you on this important and vital legislation. If you have questions or need any additional information, please do not hesitate to contact us.

Alan Mertz
President
Jason DuBois
Vice President, Government Relations

Statement of American College of Physicians

The American College of Physicians (ACP)—representing 119,000 physicians and medical students—is the largest medical specialty society and the second largest medical organization in the United States. Of our members involved in direct patient care after training, 50 percent are in practices of 5 or fewer physicians and 66 percent are in practices of 10 or fewer. Internists provide care for more Medicare

patients than any other medical specialty, making movement toward a Nationwide Health Information Network a top priority. We greatly appreciate the interest of Subcommittee Chairman Nancy Johnson and Ranking Member Pete Stark in legislative proposals to encourage the widespread adoption of electronic health records.

ACP believes the widespread of adoption of electronic health records will only be successful if we first recognize the complex issues surrounding financing, interoperability, assistance with redesign of practice workflow, and provide technical support and training. We believe Congress has an important role to play in these areas, particularly for physicians in small practices, to support the transition to a paperless office.

Background

The Institute of Medicine's (IOM) 2001 Report, "*Crossing the Quality Chasm—A New Health System for the 21st Century*," suggested that up to 98,000 Americans die each year as a result of medical errors. The report introduced the notion that many of these lives could be saved through the advantages of information technology. The IOM report cautions, however, "In the absence of a national commitment and financial support to a build a national health information infrastructure—the progress of quality improvement will be painfully slow."[1] Since then, numerous studies and other policy experts have confirmed that full adoption and utilization of health information technology (HIT) can revolutionize health care delivery by improving quality of care and reducing high medical costs.

Meanwhile, Congress and the Administration have taken initial steps to advance the adoption of an interoperable health information infrastructure model. The most significant commitment was the April 2004 announcement by President Bush calling for the widespread adoption of interoperable electronic health records within the next decade. To oversee this bold ten-year initiative, the President announced the creation of the Office of National Coordinator for Health Information Technology (ONCHIT), and named its first Director, Dr. David J. Brailer. Subsequently, ONCHIT devised a 10-year funding strategy for policymakers to consider in speeding HIT adoption nationwide. According to ONCHIT's "Framework for Strategic Action," Congress should consider several funding options, including additional Medicare reimbursement as well as the use of loans, tax credits, and grants. It also should consider the easing of fraud and abuse laws to allow the sharing of electronic hardware. Since that time, Congress has introduced dozens of bills to begin to mold the framework for adopting HIT infrastructure. Unfortunately, no single bill has made it out of both Houses.

ACP strongly supports efforts by the Administration and Congress to speed the adoption of uniform standards for health information technology (HIT). The College is committed to providing its own members with practical tools to help them improve quality. ACP's Physicians Information and Education Resource (PIER) provides ACP members—at no cost to them—with access to "actionable" evidence based guidelines at the point of care for over 300 clinical modules. PIER has also been incorporated into several electronic health record systems. It is currently in the process of aligning its evidence-based content to support a starter set of measures selected by the Ambulatory Care Quality Alliance (AQA). PIER is also creating paper order sets that imbed such quality measures so that physicians who have not made the transition to electronic health records could still utilize PIER content to support their participation in performance measurement initiatives. ACP's Practice Management Center has developed resources to help internists in the decision-making process on electronic health records and is leading an initiative to provide internists with tools and best practices to help them redesign their office processes to improve health care quality.

We also believe, however, that without sufficient financial assistance from the federal government to incentivize providers to purchase the full range of HIT, particularly those in small practices, we will be unable to achieve a smooth transition into a fully-integrated HIT society. ACP is very supportive of the initiative announced by HHS Secretary Mike Leavitt to create the American Health Information Community (AHIC), a public-private collaboration that will help develop standards and achieve interoperability of health information. This collaboration will provide a forum for interested parties to recommend specific actions that will accelerate the widespread application and adoption of electronic health records and other health information technology. **Meanwhile, we believe it is absolutely essential for**

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[1] Institute of Medicine, *Crossing the Quality Chasm—A New Health System for the 21st Century*, March 2001, and U.S. Department of Human Services, Information for Health: A Strategy for Building the National Health Information Infrastructure, Report and Recommendations from the National Committee on Vital and Health Statistics, November 15, 2001.

Congress, as a first step, to begin to fully fund pilot testing of interoperable HIT into small and large practices. Small practices, in particular, will need financial assistance for the initial start-up costs of acquiring the technology, but also financial recognition of the ongoing costs.

Privacy and Security Concerns

ACP has long recognized the need for appropriate safeguards to protect patient privacy and security. We believe that trust and respect are the cornerstones of the patient-physician relationship and to quality health care. We further believe that the presence of trust, respect, and privacy will enhance treatment by restoring confidence in the health care system. ACP recognizes that patients have a basic fundamental right to privacy that includes the information contained in their own medical records—whether in paper or electronic form.

We strongly believe that physicians—already governed by strict ethical codes of conduct, state professional disciplinary codes, and the Hippocratic oath—who collect protected health information have a duty and responsibility to protect patients from violating their privacy. Patients need to be treated in an environment in which they feel comfortable disclosing sensitive and confidential health information to a physician they can trust. Otherwise, there may be a "chilling effect" for patients to fully disclose the most sensitive of information (conditions or symptoms), thereby reducing the effectiveness and timeliness of treatment, or, they may avoid seeking care altogether for fear of the negative consequences that could result from disclosure. The discussion of moving toward an electronic health information exchange only increases the likelihood of fraud and abuse.

In 2002, HHS promulgated the Privacy Rule (45 CFR Parts 160 and 164) under legislative authority provided by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Included in the Privacy Rule is the provision that allows for the preemption of federal law provided that state law is more stringent. Unfortunately, this well-intended provision has created a patchwork of privacy laws throughout the country that has the effect of restricting the free flow of medical information. As we move toward creating a nationwide interoperable HIT system, the different laws will only serve as a hindrance in that effort.

ACP strongly supports the provision contained in H.R. 4157, the "Health Information Technology Promotion Act of 2006" that requests a 50-state study of privacy and security laws to examine how such laws will effect the flow of electronic health information. We hope that Congress will act to correct any unintended restrictions by creating a uniform federal standard with regard to the exchange of electronic health information.

Finally, the College believes that certain provisions of the Privacy Rule need to be expanded to permit the movement toward an interoperable exchange of health information. First, we believe the minimum necessary provision should be reexamined in a way that balances the need for a complete medical record with adequate protections for patients against discrimination or any other form of prejudice. Second, we believe Congress should expand its definition of "covered entities" to include any individual who accesses protected health information. Finally, we believe a private right of action should exist for all entities that knowingly, under false pretenses, or for personal gain violate the privacy or security of an individual. Patients must have assurances that adequate firewalls against unauthorized individuals gaining access to sensitive data is in place. Congress must ensure these safeguards are present.

Finanical Barriers

The single biggest barrier to achieving fully interoperable HIT across the nation is the substantial cost in acquiring the necessary technology. This obstacle is especially acute for physicians practicing in small office settings, where three-fourths of all Medicare recipients receive outpatient care.[2] An additional related barrier is that public and private payers, not the physicians, will realize the savings from physician investment in acquiring the necessary HIT (i.e., electronic health records, electronic prescribing, clinical decision support tools, etc).

The initial start-up costs for the purchase of a fully interoperable HIT system can be substantial. **Depending on the size of the practice and its applications, acquisition costs on average range from \$16,000 to \$36,000 per physician.**[3]

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[2] Center for Studying Health System Change, "Most Medicare Outpatient Visits Are to Physicians With Limited Clinical Information Technology," July 2005.

[3] Congressional Research Service, "Health Information Technology: Promoting Electronic Connectivity in Healthcare," The Library of Congress, April 13, 2005.

(The Harvard Center for Information Technology Leadership estimates HIT systems cost about $29,000 per physician). The ongoing costs associated with training, upgrades and maintenance, and system support of the HIT system make these estimates substantially higher over the lifetime of the practice.

Unfortunately, the savings from interoperable HIT will largely go unrecognized for physicians making the investment to convert their practices. In fact, it's more likely the majority of the savings from physician investment will be recognized by payers and patients—through a reduction in duplicative care, the lowering health care administrative costs leading to lower health insurance rates, and avoiding costly medical errors—not to the providers that pay the initial and ongoing implementation costs. **ACP strongly believes that physicians' collective and individual contributions must be recognized in order to achieve Medicare and Medicaid savings through HIT adoption. Current reimbursement policies should allow for individual physicians to share in the system-wide savings that are attributable to their participating in HIT and other quality improvement programs.**

While the College and the physician community recognize the great potential for improving the overall quality of care that HIT brings, the majority of small practices cannot afford to expend the necessary capital to make the initial investment. For physicians dealing with a multitude of financial issues—ranging from low reimbursement under Medicare and Medicaid, declining fees from managed care, the rising costs of medical malpractice insurance, and the cost of compliance under increasing state and federal regulation—the majority are not in any financial position to make the initial $16,000 to $36,000 investment.

Even for those physicians who able to afford the initial costs, many challenges await. As described in the August 2, 2005 *Annals of Internal Medicine*, the conversion to electronic medical records impacts a practices finances, productivity, and office environment. According to the authors of this 4-internist medical practice in Philadelphia, Pennsylvania, "Its financial impact is not clearly positive; work flows were substantially disrupted; and the quality of the office environment initially deteriorated greatly for staff, physicians, and patients. That said, none of us would go back to paper health records, and all of us find that the technology helps us better meet patient expectations, expedites many tedious work processes (such as prescription writing and creation of chart notes), and creates new ways in which we can improve the health of our patients."

The experience of this small practice is not atypical. While this practice should be commended for weathering the myriad of challenges in adopting electronic health records, Congress needs to recognize that most physician practices are not financially positioned to absorb the many hardships that lie ahead.

The Need for Congressional Involvement

The current Medicare physician reimbursement system, the Sustainable Growth Rate (SGR), does not reward physicians for quality. Because physicians are paid on a per-procedure or per-service basis, the Medicare reimbursement structure emphasizes volume over quality. Meanwhile, physicians are facing another estimated 4.6 percent payment cut in January 2007. These cuts in payments deprive physicians of the resources needed to invest in health information technology and quality improvements.

In recognition of the need for a Medicare reimbursement system that rewards innovation and quality, Congress is examining the role that value-based purchasing programs might play in the Medicare program. **We commend Chairman Johnson for her leadership on developing legislation, H.R. 3617, "the Medicare Physician Value Based Purchasing Act of 2005," to begin linking payments to quality, thereby creating an incentive for HIT.** We continue to support the bill, but we also recommend that the Subcommittee consider a legislative framework that would go beyond grafting pay-for-performance on the current dysfunctional payment system to one that would create sufficient and sustained incentives for quality improvement, efficiency, and physician-directed coordination and management of care for patients with multiple chronic diseases.

ACP strongly believes a solution to this problem lies in changing the Medicare physician payment policies to reward those physicians who fully incorporate all aspects of HIT and participate in reporting on endorsed performance measures.[4]

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[4] Under today's Medicare payment formula, physician payment is based upon several factors: relative value units (RVUs) for each service, reflecting the relative amount of physician work effort, practice expenses, and malpractice insurance expenses involved with furnishing each service; a dollar conversion factor that translates these RVUs into monetary payment amounts;

We believe an element of this concept should include reimbursement for the use of HIT, leading to widespread adoption of electronic health records in physician practices.

As a first step, the College recommends Congress consider legislation that builds into the Medicare physician payment system an add-on code for office visits and other evaluation and management (E/M) services. This would fairly recognize the *ongoing*, everyday costs associated with maintaining such systems. This payment mechanism should identify that a service was facilitated by electronic health data systems, such as electronic health records, electronic prescribing and clinical decision support tools, and reimburse accordingly. This legislation should be rolled into a broader reform of the Medicare payment system that includes quality measures. Of course, this innovative way of reimbursing physicians will come at a cost, so Congress should seek to reform the scoring models used by the Congressional Budget Office (CBO) to more accurately reflect savings from efficiencies and cost savings that will result from the use of electronic health records and quality initiatives.

In addition, Congress should also allocate the necessary funding for small practices to make the *initial* HIT investment to purchase the necessary hardware and software. The majority of bills that have been introduced in the 109th Congress only utilize grants, loans, tax credits, or a combination of the three. We believe those funding mechanisms alone are insufficient to put the necessary HIT systems into the hands of small physician practices.

Also, we specifically urge the Congress to pilot test a new model for organizing and delivering primary and principal care that addresses the fact that the U.S. health care system is poorly prepared to meet the current, let alone the future health care needs of an aging population. This model, called the advanced medical home model, is based on the premise that the best quality of care is provided not in episodic, illness-oriented, complaint-based care, but through patient centered, physician-guided, cost-efficient, longitudinal care that encompasses and values both the art and science of medicine.

Attributes of the advanced medical home include promotion of continuous healing relationships through delivery of care in a variety of care settings according to the needs of the patient and skills of the medical providers. Physicians in an advanced medical home practice are responsible for working in partnership with patients to help them navigate the complex and often confusing health care system. They provide the patient with expert guidance, insight and advice, in language that is informative and specific to patients' needs. In the advanced medical home model, patients will have a personal physician working with a team of health care professionals in a practice that is organized according to the needs of the patient.

ACP envisions that qualified practices will have the following kinds of services in place:

- Primary care physicians who practice in an advanced medical home would be responsible for partnering with the patient to assure that their care is managed and coordinated effectively;
- The practice would use innovative scheduling systems to minimize delays in getting appointments;
- Physicians in the advanced medical home would use evidence based clinical decision support tools at the point of care to assure that assure that patients get appropriate and recommended care;
- They would partner with patients to help patients with chronic diseases, like diabetes, manage their own conditions to prevent avoidable complications. Patients would have access to non-urgent medical advice through email and telephone consultations;
- The practice would have arrangements with a team of health care professionals to provide a full spectrum of patient-centered services; and
- Advanced medical home practices will also be accountable for the care they provide, by using health information technology to provide regular reports on quality, efficiency, and patients' experience measures.

This effort would complement ongoing and planned CMS pilot programs utilizing HIT such as the Medicare Physician Group Practice Project, the Medicare Care Management

Performance Demonstration (MMA Section 649), and Medicare Health Support Pilot

(MMA Section 721) and Medicare Health Quality Demonstration Program (MMA

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and geographic practice cost indexes (GPCIs) for physician work, practice expenses, and malpractice insurance expenses to reflect differences in physician practice costs among geographic areas.

Section 646). ACP recommends that Congress expand these demonstration pilots, where appropriate, to a larger number of states (large and small) and more practices in each state; and allowing all participating practices to receive financial incentives not just those in study group.

Once developed, HIT standards will need real-world pilot testing. This should come as no surprise to Congress given the dire situation we found ourselves in 2003 with the implementation of standards mandated under HIPAA Transaction and Code Sets Standard. As with HIPAA Standards compliance, implementation of HIT standards will require transition and a significant amount of pilot testing by the full range of health care providers from all sectors with adequate HIT in place. Testing must include physicians in solo/small and large practice settings (rural and urban areas), psychologists, hospitals, community health centers, skilled nursing facilities, laboratories, and pharmacies. All participants in the pilot must utilize the full range of HIT systems and the necessary ongoing training must be provided. **Therefore, we believe Congress must provide the necessary funding to ensure adequate pilot testing of HIT standards across all health care sectors to determine feasibility, disclose barriers, and develop solutions to ensure a smooth transition.**

Finally, the College believes Congress should pass provisions also included in H.R. 4157 that seek to lift the prohibition of health care entities assisting physician practices from purchasing HIT. While we do not believe the majority of potential Donors protected by the proposed exceptions and safe harbors will have the necessary financial resources to make a major impact regarding implementation of this technology, there will be some who are financially able to offer this kind of assistance and it is important we allow this transaction to occur.

In summary, the College believes Congress should take the following legislative actions to speed the adoption of HIT:

1. Reform the Medicare reimbursement formula to specifically reward quality and the use of electronic health records;

2. Provide funding through a combination of grants, loans, and tax credits to assist small physician practices absorb the initial expense of acquiring electronic health records;

3. Direct CMS to expand demonstration projects using the medical home concept and expand MMA's Section 649, Section 721, Section 646;

4. Reform the scoring models used by CBO to more accurately reflect efficiencies and cost savings from the use of electronic health record technology;

5. Pilot test the use of the full range of HIT and standards across of health care sectors;

6. Develop a uniform federal mandate for privacy and security; and

7. Reform the Anti-kickback and Stark Self-referral laws to allow health care entities to directly collaborate with physicians to purchase health information technology without fear of violating the law.

Legislation in the 109th Congress

In the 109th Congress, a flurry of legislative proposals have been introduced to define the federal role in speeding the adoption of HIT. ACP is supportive of many of the bills that have come forward, especially those that we believe will lead to the achievement of universal acceptance and widespread adoption of HIT. While not an exhaustive list of legislation supported by ACP, the College believes the following bills present the best opportunity to advance adoption of HIT:

The legislation, H.R. 4157, the "Health Information Technology Promotion Act of 2006," introduced by Chairmen Johnson and Nathan Deal, has many favorable provisions to speed adoption of health information technology. In particular, the College is supportive of efforts to create a safe harbor to the Federal Anti-kickback Statute and an exception to the Self-Referral Law, and the authorization to study and reconcile the variation of State and Federal standards established under the HIPAA. However, we have concerns that conversion to a more granular coding system (ICD–10) is unwarranted at this time and will create an unnecessary burden and administrative hassle to practicing physicians. Finally, we believe the legislation fails to make any significant attempt to address the financial issues facing small physician practices. However, we acknowledge that H.R. 3617 may be a more appropriate vehicle to address these concerns.

The College is also supportive of legislation, H.R. 4641, "the Assisting Doctors to Obtain Proficient and Transmissible Health Information Technology (ADOPT HIT) Act of 2005," introduced by Representatives Phil Gingrey and Charlie Norwood. This legislation would allow physician practices to deduct the purchase of HIT by increasing the small business tax deduction under Section 179. We believe this approach will capture many physician practices who

are struggling to absorb the initial costs of HIT, but would have a greater impact if combined with changes in Medicare payment policies, as discussed above, to support the ongoing expenses associated with use of health information technology to improve quality.

We strongly believe that the most effective way to encourage the widespread adoption of HIT is to combine federal assistance with the initial costs of acquiring technology, and the ongoing costs associated with training, upgrades, and lost productivity. **The College is particularly supportive of the bipartisan bill, H.R. 747, the National Health Information Incentive Act," sponsored by Reps. Charles Gonzalez (D–TX) and John McHugh (R–NY), because it specifically targets those small physician practices who are in need of the most financial assistance**. Like most of the legislative proposals introduced so far, H.R. 747 offsets the initial start-up costs and ongoing training and maintenance costs of acquiring interoperable HIT systems by providing grants, loans, and refundable tax credits. But more importantly, the legislation builds into the Medicare physician payment system an add-on code for office visits and other evaluation and management (E/M) services, care management fees for physicians who use HIT to manage care of patients with chronic illnesses, and payments for structured email consults resulting in a separately identifiable medical service from other E/M services. These fees would be triggered if the procedure or service was facilitated by an electronic health data system (such as electronic health records, electronic prescribing and clinical decision support tools) when used to support physicians' voluntary participation in performance measurement and improvement programs. Additionally,H.R. 747 takes the appropriate step of establishing two-year pilot testing of the standards and the determining quality improvements and cost savings of the integration of HIT.

In addition, the College is also strongly supportive of the bipartisan bill, S. 1227, the "Health Information Technology Act," introduced by Sens. Debbie Stabenow (D–MI) and Olympia Snowe (R–ME). Like the Gonzalez-McHugh bill, S. 1227 includes one-time tax credits and grants for the purchase of HIT as well as Medicare physician payment changes that recognize the ongoing costs in maintaining HIT by authorizing adjustments to Medicare payment when an identifiable medical service is provided using HIT.

In summary, the College strongly believes Congress should provide the necessary funding to offset the initial costs in obtaining HIT, but it should also recognize the unquantifiable and ongoing costs in utilizing HIT. It is this combination of *one-time* and *on-going* financial incentives put forward by H.R. 747 and S. 1227 that will substantially speed HIT adoption and improve access to physician practices with HIT, resulting in tremendous system-wide savings. **Congress should recognize the collective and individual contributions needed to achieve Medicare and Medicaid savings through the adoption of HIT. Therefore, we believe funding initiatives should allow for individual physicians to share in the system-wide savings that are attributable to their participating in HIT and other performance measurement and improvement programs. We believe this concept dovetails nicely with Chairman Johnson's legislation, H.R. 3617, "Medicare Physician Value Based Purchasing Act of 2005," and support its passage.**

Conclusion

ACP is pleased that the House Committee on Ways and Means Subcommittee on Health is examining the congressional role in accelerating the adoption of health information technology. We strongly believe Congress has a very important function in promoting the adoption of uniform standards and providing the necessary initial and ongoing funding mechanisms to assist small physician practices to adopt and utilize HIT. The benefits of full-scale adoption of interoperable HIT will be significant, leading to a higher standard of quality in the U.S. health care system. Unfortunately, without adequate financial incentives, small physician practices will be left behind the technological curve and their patients with them. We eagerly look forward to working with the Subcommittee to make the widespread adoption of electronic health records a reality.

Statement of David G. Schulke, the American Health Quality Association

Good afternoon. My name is David Schulke, and I serve as the Executive Vice President of the American Health Quality Association (AHQA), the national associa-

tion representing Quality Improvement Organizations (QIOs) and professionals working to improve the quality of health care in communities across America. It is my pleasure to provide testimony today about health information technology (HIT) and a new initiative providing hands-on help to physicians in every state and territory in the United States.

As many as 98,000 Americans die each year from medical errors while receiving hospital care, with another 90,000 serious or fatal preventable adverse drug events occurring in the community-dwelling elderly each year. That revelation in a landmark 1999 Institute of Medicine report alerted the nation to a significant challenge and spurred hundreds of initiatives at the local and national levels to reduce medical errors and improve health care quality. Medicare and the national network of QIOs have been at the forefront of these efforts.

At the core of QIO quality improvement work is the identification of safer and more effective care processes, and the promotion of these clinical practices to improve patient safety and reduce medical errors. Under a performance-based three year contract with Medicare, QIOs work with thousands of hospitals, doctors, nursing homes, home health agencies and health plans across the country to help prevent disease, promote patient safety, and improve the delivery of high quality, evidence-based care. QIOs are now promoting HIT in hospitals, physician office practices, and home health agencies, based on growing evidence that effective use of HIT can improve both quality and efficiency in health care.

Helping Physicians Adopt Health Information Technology

The QIOs' experience with helping physicians adopt HIT began two years ago in a four state pilot project known as the Doctor's Office Quality—Information Technology project, or DOQ–IT. The aim of this project was simple—to achieve better quality outcomes for patients and improve efficiency for physicians by helping them adopt Electronic Health Records (EHRs).

Under the DOQ–IT project, QIOs in California, Utah, Arkansas and Massachusetts collectively helped nearly 1,000 practices adopt HIT. The QIOs provided assistance throughout each phase of HIT adoption, from assessment and planning to selection, implementation, evaluation and improvement. These QIOs helped practices to:

- Assess their readiness for HIT,
- Develop a project plan and timeline that takes readiness gaps into account,
- Understand potential return on investment (ROI),
- Identify the range of functionalities needed in an EHR,
- Evaluate different products in a crowded market,
- Select a product that meets their needs,
- Know what to expect in contracting,
- Redesign workflow and care processes, and
- Use of all of the capabilities of the installed HIT system to improve care and efficiency.

What we learned from the pilot project is that providers and practitioners need help. While financial help is of paramount importance, and I know that the Chairwoman's legislation begins to provide some assistance in this area by addressing some anti-kickback provisions of law, the truth is that even free equipment and software would not be well utilized without substantial changes to clinical operations. Physicians need help from independent organizations that can be there for them throughout the process of adoption, implementation and effective use of HIT. They need support from systems change experts who can help ensure that care processes are redesigned to reflect best practices. Providers also need support to ensure that they are utilizing their HIT system to its fullest capacity. As Members of the Subcommittee well know, the promise of HIT lies not in simply automating current practices, but in transforming them. If the result of our policies is merely to persuade providers to buy expensive EHR systems to automate practices that are inefficient and produce poor quality, all we will have accomplished is the proliferation expensive, inefficient and poor quality systems.

This hands-on support is needed because literature and experience tell us that as many as half of all EHR implementations fail for one reason or another, often because practices did not go through the rigorous preparation and development necessary for success.

The four QIOs in the DOQ–IT pilot spent considerable time trying to understand causes of failure and address them in their process change models. From the pilot, we know that some things are critical to success, for example, having a physician champion to lead the project and holding regular staff meetings. The QIOs created "readiness assessments" to gauge where the practice is with respect to critical suc-

cess factors. When these factors were weak or missing, the QIOs helped build them into the practice's project plan and timeline. By increasing awareness and use of these best practices, QIOs contributed to physician success.

But what about the ten to fifteen percent of ambulatory practices already using EHRs? Why did so many of these doctors come to the QIOs asking for help?

The reason is that these practices know that their systems are capable of much more than simply serving as an electronic record of their care. In Utah, for example, one clinic had been using their EHR system for seven years, but had never turned on the clinical decision support or disease management functions because using those functions on a regular basis simply did not fit into their daily workflow. The clinic asked their QIO, HealthInsight, for help. HealthInsight showed the clinic how to evaluate their existing workflow and redesign their care processes so that the practice could utilize these high-level functions of their IT equipment—functions which are so central to improving quality.

This illustrates why it is critical for QIOs to help physicians both with and without existing HIT systems—helping one and not the other leaves a large gap by failing to address both effective adoption and effective use of HIT.

HIT Assistance Now Available Nationally

Right now, QIOs across the country are doing just that, based on the work of the pilot state QIOs, HealthInsight, Lumetra (the California QIO), the Arkansas Foundation for Medical Care, and MassPRO (the Massachusetts QIO). All QIOs have been trained on the models they used and the lessons they learned. In August of last year, QIOs received funding from Medicare to support over 4,000 primary care practices across the country during the next two years, and 3,000 practices have already signed up for assistance from their local QIO in just the past eight months. This is despite the fact that QIOs don't give physicians any money to help them purchase or implement these systems.

This assistance is already proving to be highly valued by physicians in the field. As a California family physician told us, he is glad he worked with his QIO, Lumetra, on EHR adoption. Without their expert help, he says, "I would probably have gotten so fed up that I would have missed out on what is going to be a literal transformation in the way that I practice medicine."

Of the total number of practices QIOs will work with, at least 80% are the kind of practices that most need help—small and medium sized practices with no HIT systems to begin with. And these practices aren't just in suburban areas—they are urban, and they are rural. In addition, to reduce health care disparities, QIOs have made a particular effort to reach out to practices treating underserved patients. To date, nearly 700 of the 3,000 practices currently working with their local QIO treat a significant number of underserved patients.

QIOs begin by examining the practice's readiness, which includes reviewing and developing the practice's culture and leadership, financial planning, systems and infrastructure needs, functionality requirements, workflow issues, and more. QIOs then offer assistance throughout the adoption continuum in areas including:

- Developing a project plan and timeline
- Hardware and infrastructure needs
- Resources for system comparisons and selection, including site visits and access to EHR selector tools
- Functionality requirements and preferences
- Contracting principles and guidelines Workflow mapping Change management and preparation
- Strategies for handling existing data
- Planning for appropriate staff training
- Guidelines for system maintenance and availability
- Go-live planning
- Optimal use of the software
- Reporting quality data
- Quality improvement processes and tools

QIO assistance does not supplant vendor assistance—QIOs do not provide technical support for installation, programming, interface development, application training or troubleshooting software and hardware glitches. QIOs remain vendor neutral, although they do inform practices about vendors that either currently have or are planning to have the ability to extract a specific quality performance measure set from the EHR.

The performance measures that comprise this measure set are those that have the greatest impact on the Medicare beneficiary population, including heart disease, diabetes, hypertension, heart failure and preventive measures. These measures—

known as the Doctor's Office Quality (DOQ) measures—were developed in concert with the American Medical Association, the National Quality Forum and others.

Practices that report the DOQ measures will be able to receive from their QIO customized reports on the quality of their patient care. QIOs can then work collaboratively with the practice to identify and implement strategies for making any necessary changes to workflow or care processes to improve on the performance measures.

Using HIT beyond patient care to report data, measure quality, and undertake improvement will give participating physicians a major leg up on what is likely to be the future of health care reimbursement—pay-for-performance.

Pay-For-Performance

A recent report from the Institute of Medicine noted, ". . . it is clear that a large need exists to help providers improve their quality of care and that the QIOs can help meet this need." The report goes on to recommend that "The QIO program must become an integral part of strategies for future performance measurement and improvement in the health care system."

Experience in community-based quality improvement shows that it is not enough to simply measure quality, or to publicly report quality data. It is unlikely even payment incentives will be sufficient to produce the results Congress and the public are demanding. A 2004 *Health Affairs* study by Rosenthal et al reviewed several incentive programs, concluding that "aligning providers' financial incentives with quality goals may be a necessary precursor to improvement, but it is probably not sufficient. Rather, quality programs should be viewed as part of a broader strategy of promoting health care quality through measuring and reporting performance, providing technical assistance and evidence-based guidelines, and, increasingly, giving consumers incentives to select higher quality providers and proactively manage their own health."

Quality does not improve on its own—it takes hard work. Physicians, nurses, pharmacists and others benefit from help identifying the cause of quality gaps and then learning how to implement proven techniques to close those gaps. QIOs offer the only nationwide field force of experts dedicated to understanding the latest methodologies in quality improvement and working with doctors and other professionals at the local level to use those techniques effectively. Their hands-on local assistance will be key to helping physicians succeed under future pay-for-performance or value-based purchasing programs.

There is evidence that working with health care professionals accelerates the rate of improvement. The 2005 AHRQ National Healthcare Quality Report shows that health care providers working with their local QIO improved at a faster pace than those who did not. In two areas of care, heart attack and pneumonia, the improvement rate was four times the rate of all other measures nationally. Improving the quality of heart attack and pneumonia care saves both lives and money.

The primary role for QIOs in pay-for-performance is to support providers through technical assistance and the provision of evidence-based guidelines. We agree with the IOM's finding that QIO assistance must be a central part of future performance improvement initiatives because it reflects our experience that success in quality improvement happens faster when doctors work in partnership with experts who understand cutting-edge improvement techniques.

Our work with physicians to adopt and use HIT effectively also provides three key lessons that are relevant to the pay-for-performance dialogue: First, successful adoption and effective use of HIT improves the quality of care and therefore better positions health care providers for financial success under pay-for-performance.

Second, EHR vendors tell us that it is easier for them to work with a physician who has also worked with the QIO because the practice is better prepared and thus more likely to succeed. Increasing the number of physicians who successfully and efficiently adopt EHRs can help motivate change in others and accelerate the pace of EHR adoption nationally.

Third, successful EHR adoption helps build the electronic infrastructure for data collection. This infrastructure is key to successful incentives programs because claims data alone—which largely reflect processes of care and not outcomes of care—do not provide a full picture of patient self-management or care quality overall. Data collection from EHRs is potentially more accurate and provides a better picture of the true quality of care.

Interconnected Health Care:

The most complete picture of patient care will not come from EHRs alone, but from an interconnected health care system where authorized providers have access to secure, accurate and comprehensive patient information at the point of care, in

real time. I know that the Chairwoman has been a long-time champion of efforts to mobilize data across institutions in the health care system, and we support your efforts to move this promising field forward.

Quality measurement and reporting, combined with improvement assistance, are well known strategies for improving care. Yet the ability of providers to perform at the highest levels of excellence often depends on clinical data that are stored in disparate organizations across the health care system. Health Information Exchange (HIE) can help accelerate efforts to improve quality, safety and efficiency by delivering more comprehensive information about the patient at the point of care. Availability of this critical information is an important tool to help us address medical errors, such as the dispensing of contraindicated prescriptions by two separate physicians treating the same patient.

I am pleased to share with you today findings from a recent report from the American Health Quality Foundation and the eHealth Initiative which finds that QIOs in 41 states and the Virgin Islands are currently supporting local, regional, and statewide initiatives to develop health information exchange networks, many in leadership roles.

QIOs are convening stakeholders and helping communities reach consensus on the goals, operations and functions of HIE initiatives. This is an especially valuable role for QIOs because of their experience and relationships in all settings of care. For example, to date, nursing homes and home health agencies often have not had a meaningful role in many local HIE initiatives, and yet these entities would benefit significantly from both HIT adoption assistance and community-based HIE. QIOs are leading the way in bringing diverse stakeholders together across communities so that all health care interests are engaged in a common agenda.

Many QIOs are participating in governance of these emerging HIE entities, and several are also helping their communities develop policies for information sharing, sustainable business plans and technical infrastructure. The report finds that, because of their structure, function, history and expertise, QIOs are helping accelerate the formation of these HIE networks.

Future QIO Assistance

As I've outlined today, the field force provided by QIOs offers health care providers in every state free and needed assistance for improving quality. From supporting and accelerating physician adoption of EHRs to working with nursing homes, hospitals, home health agencies and others, QIOs are helping health professionals utilize the latest techniques in quality improvement to eliminate medical errors, reduce suffering and improve the quality of life for patients across the country.

Recent studies from RAND and others tell us that Americans get only about half of the recommended care for their medical conditions. As HIT, pay-for-performance and health information exchange increasingly become vital tools for transforming quality, all providers will need performance improvement assistance from quality experts like QIOs.

The QIO program represents the largest coordinated federal investment in improving health care quality—right now, that investment accounts for less than one tenth of one percent of overall Medicare spending. As Congress considers legislative action to realign incentives through pay-for-performance in support of health care quality and accountability, we hope you will encourage the expansion of this invaluable program to become a central fixture in our collective drive to provide the right care to every patient, every time.

Statement of Community Clinics Initiative

This statement is submitted for the record on behalf of the Community Clinics Initiative (CCI), a unique collaboration between the Tides Foundation and The California Endowment, that began in 1999 to provide resources, evidence-based programming and evaluation, education and training to support community health centers and clinics. Through information sharing and major grants, CCI acts as a catalyst to strengthen California's community clinics and health centers to improve health outcomes in underserved communities. The state's community clinics offer high quality, low- and no-cost care, often in rural and inner city areas, providing a lifeline for millions of uninsured and underinsured Californians.

Over the past 5 years, CCI has invested close to $48 million to support Community Clinics and Health Centers throughout California to strengthen their information management capacity for more effective use of technology tools to improve busi-

ness efficiencies, improve patient health outcomes, and advocate for health needs in communities throughout the state. Over time, CCI has funded and supported through technical assistance, the development of basic technology systems in clinics, such as software, hardware, connectivity, staffing and training to more than 90% of clinics and health centers.

We would like to share with you information about our work in California and we share the lessons that we have learned in the hopes that they can help inform the national conversation around HIT.

Through programs and grants in technology, capacity building and leadership, CCI ensures that clinics remain vital partners in building healthier communities. Grantees encompass 90 percent of California's community clinics and regional consortia, securing CCI's role as a major player in the field. Individual awards enable clinics to convert to electronic medical recordkeeping, improve or expand patient facilities, use software to share data among clinics in a network, or train its staff in fundraising. These enhanced capabilities allow clinics to better track health status, care for more patients, achieve diverse revenue sources, reduce administrative costs, expand opportunities for shared learning and collaboration or advocate for community health needs.

It is clear that patient safety, health care quality (especially for populations with chronic diseases), efficiency, and cost savings can be improved through the effective use of clinical information technology. And, while technology alone cannot address all of the quality and efficiency problems, its adoption is associated with changes in how care is provided.

As community clinics and health centers have become more technology "savvy" and the capacity in clinics, for data collection and data analysis more mature, we see the potential for the proliferation of technology enabled quality improvement in the field.

The California experience has taught us a lot about what it takes for community clinics and health centers to successfully implement HIT. We also are learning that when they have the appropriate resources and support, community clinics can be leaders and innovators in using technology to improve health outcomes.

As we observe the increasing momentum for HIT at the federal level, we find that appropriate understanding and consideration of the unique HIT needs of community clinics are not being addressed. Unless careful attention is paid to realistic HIT strategies for these clinics, we are at risk for having HIT increase rather than decrease the disparities in care. We need to take steps to ensure that the patients in community clinics have the same benefits of technology that will be available to patients outside the safety net.

Most important is the need for creative strategies to finance the significant up front investment costs for HIT in clinics. Current strategies promoted by the Administration and spearheaded by Dr. David Brailer are market driven and rely heavily on the private sector and assumed return on investment. While there is skepticism about this approach for the broad health care universe, it seems clear that reliance on these market forces will certainly fail community clinics. We believe that there is little if any financial return on these investments for CCHC's, and in fact, most will incur financial losses and potentially even see a decrease in access if resources are diverted to pay for these systems. We already know that the financing mechanisms of community clinics, which rely heavily on Medicaid reimbursement and public grant programs, make direct return on investments for clinics unlikely. If cost savings do occur, they occur downstream from the clinic, benefiting hospitals and payers such as Medicaid through lower costs for acute care, in-patient stays and emergency room visits.

As interest in new HIT legislation in the Congress grows, we would ask you to keep in mind several important opportunities:

- We need mechanisms to ensure that cost savings are driven back upstream to the clinics to help fund HIT investment.
- It seems logical that the HIT and the Medicaid debate be joined. Investments in HIT have the potential to make the delivery of community based health care more efficient and to improve health outcomes through the improvement of quality of care.
- Funding for technology must be based on the true costs of technology innovation. As we have described, the costs of hardware and software are only a small portion of the true organizational costs. Some estimates suggest the cost of EHR implementation ranges from $20,000–$50,000 per physician.
- Most current legislation suggests special attention be given to specific classes of providers, such as private practices. We encourage you to grant similar status to community based clinics.

- Many HIT bills propose establishing loan funds to finance HIT investment. While loan funds have the potential to be important resources for community clinics, they must be structured to address clinics' unique financing and reimbursement mechanisms. Specifically, grant funds should be made available to finance the up-front costs necessary for planning; underwriting criteria must take into account the financial structures of clinics and payers such as Medicaid need to recognize ongoing IT costs and debt service payments in setting reimbursement rates.

We hope you will use CCI as a resource in the days and months ahead. Because of the work we have done, we have the experience and resources to be good partners in this conversation around HIT. And we hope together we can reach safety net communities in clinics and health centers to bring HIT into their lives and improve their level of care.

Should you have any questions, please contact:

Ellen Friedman, Vice President and Managing Director or Jane Stafford, Senior Program Officer, Community Clinics Initiative

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Statement of Gregory C. Simon, FasterCures

FasterCures is pleased to have this opportunity to participate in the conversation on the importance of health information technology (IT) and on public and private efforts to increase the adoption of health IT. We appreciate the continued interest in this field by this Subcommittee. We especially applaud you, Chairman Johnson, for the leadership you have demonstrated over many years in championing the establishment of a national interoperable health information infrastructure.

We share the goal of improving the quality and efficiency of healthcare in the United States through the widespread adoption of interoperable health information technology. Indeed, there is general agreement that electronic medical records will reduce healthcare costs, avoid medical errors and improve patient care. Each one of those issues is important. But the real savings, both in healthcare costs and, more importantly, in eliminating human suffering, will come from curing disease and saving lives. At *FasterCures*, we believe we must link care to cures—and that the use of electronic medical records data in research is critical in that effort.

FasterCures is a nonpartisan, nonprofit organization whose goal is to save lives by saving time in the discovery, development, and deployment of treatments and cures for deadly disease. We are independent of any interest or industry groups. Our mission is to evaluate the current system of medical research; to identify inefficiencies, misplaced priorities, and conflicting incentives that inhibit the pace of discovery and development; and to propose and pursue improvements to the existing system. We seek to enhance and accelerate the efforts of those creating and overseeing the creation of safe and effective treatments and cures: health, research advocacy, and funding organizations; scientists; medical professionals; policy professionals; clinicians; and patients themselves.

The current clinical care and biomedical research infrastructures operate largely independent of one another. Clinical and biomedical researchers generally cannot access data collected in the clinical care process for use in studying the origins and course of disease. Similarly, data that are collected on a patient in a clinical trial generally do not become part of a patient's medical record. In other words, potentially life-saving research results do not flow rapidly from "bench to bedside," and real life healthcare outcomes and observations that should be shaping the next generation of biomedical research flow back to the "bench" even more slowly, if at all.

The development of the Nationwide Health Information Network and the broader use of health IT present a unique opportunity to accelerate the search for cures. We can do so if we take steps during the initial phases of standards development and system design to enable the research use of information collected in the patient care process. After all, we don't want to build a new superhighway of health information and then have to dig it up in a few years to make it capable of supporting research needs.

In order for that to happen, the vital, yet often too narrow, focus of the NHIN to support healthcare delivery must be expanded to support the entire healthcare continuum, including health research.

The ability of researchers to access and analyze the clinical information contained in millions of medical and personal health records, with appropriate privacy and human subject protections, could speed the discovery of new therapies beyond anything imaginable today. A system that supports data sharing from care settings to

the researcher also can support dissemination of results from the researcher to the practitioner and the patient, thereby speeding the translation of research results into clinical practice. I do not want to diminish the importance of ensuring that safeguards are in place to ensure patient privacy protections. But we should not let fears alone prevent us from recognizing the tremendous research potential of electronic medical records.

The potential benefits of a research-inclusive EMR system would be to speed clinical trials by quickly identifying potential enrollees; enhance the monitoring and identification of adverse drug reactions, in effect creating "virtual clinical trials" of thousands of patients to study the impact of approved drugs; permit the early identification of public health threats; provide the research community access to a broader and more diverse patient population; detect patterns of health and illness in a given population; and help researchers form hypotheses about disease initiation and progression.

In our report "Think Research: Using Electronic Medical Records to Bridge Patient Care and Research," we examined the current landscape of electronic medical records databases and profiled some of the innovative health systems that are pioneering the use of EMRs as a research tool. Because we know there is a long way to go before EMRs can be widely used in research, several institutions and government agencies have forged ahead to find ways to meld clinical data with research goals. These institutions include:

- **Mayo Clinic: Rochester, Minnesota.** The Mayo Clinic has converted completely to an EMR system as of July 2004 and has been using paper-based medical records in research for more than 80 years. Mayo conducts more than 4,000 clinical trials each year, and nearly every trial relies on information from medical records. In addition, researchers from IBM and Mayo are using supercomputing technology and applying customized algorithms, data mining, and pattern recognition to uncover correlations between particular proteins, genetic markers, patient outcomes, and other factors that could lead to new diagnostics and treatments.
- **Regenstrief Institute: Indiana University School of Medicine.** Over the past three decades, Regenstrief has developed one of the nation's first EMR systems, along with the nation's only citywide EMR system, which allows doctors in emergency rooms to view as a single record all previous care at any of 11 hospitals. The records have been useful for prospective, retrospective, epidemiological, longitudinal, and cohort studies, and for enhancing clinical trials data sets.
- All **Veterans Health Administration** medical centers have EMRs. Although VHA's computerized record activity began in the late 1970s, it has evolved over time to become VistA, VHA's current health information system. As a consequence of VA's comprehensive use of medical information technology, a wide variety of electronic databases have been created, many of which include patient-specific clinical information that could be used for research purposes. VA researchers routinely access these databases as well as patient records (with consent) primarily to conduct health services research.

To make the best use of medical records data in research, we need a national effort that builds on and goes well beyond the work of the pioneering institutions noted in the report. That is why we have been working with leaders of organizations dedicated to realizing the healthcare and health research benefits of information technology through the creation of the NHIN. On May 9th, *FasterCures* is co-hosting with the National Center for Research Resources at NIH and the Agency for Healthcare Research and Quality an expert meeting to develop an action agenda for the inclusion of clinical research in the NHIN.

In order to integrate research needs into the development of the NHIN, there must be a framework for defining the characteristics and development priorities of the research-enabling network. Working with representatives from the Markle Foundation and the National Cancer Institute, *FasterCures* developed the following Guiding Principles as a starting point for such a framework.

1) Enable Bi-Directional Data Exchange

The NHIN should support access to health information and healthcare data collected in the course of routine medical care and from other sources to improve research capabilities. Similarly, it should support widespread access to research data to improve health and healthcare.

2) Encourage Optimum Use of Phaient Data

The NHIN should provide incentives to promote and facilitate the broadest and most effective use of patient care data in clinical research and ensure that clinical research results be widely available and integrated into decision-support tools to benefit patient care and improve personal health decisions.

3) Facilitate Collaborative Research

The NHIN should have the capability to serve as a broadly enabling research infrastructure that promotes the sharing and reusing of clinical research results to facilitate collaborative research.

4) Require Common Data Standards

The NHIN should require that a single set of standards be developed and adopted for the collection and exchange of data across all health communities, including the research community.

5) Create a Network of Networks

The NHIN should support a federated and interoperable system that links to pre-existing and future networks, creating a "network of networks."

6) Be Technology and Content Independent

The NHIN should be designed with the flexibility to respond to the evolution of technology, which creates potential new sources and uses of data.

7) Safegaurd Privacy and Assuring Informed Consent

The NHIN must be capable of ensuring compliance with appropriate requirements for patient privacy, informed consent, and confidentiality.

It has been nearly two years since the President Bush established the Office of the National Coordinator of Health Information Technology (ONCHIT) and called for the widespread adoption of electronic health records by 2014. Those announcements, and the continued leadership of the President, Secretary Leavitt, Dr. David Brailer and key members of Congress on this Subcommittee and beyond, have catalyzed a more organized federal effort to foster a national health information infrastructure to make our healthcare system more efficient and effective. Now, it's time to make sure that health cures are integrated into this process as well. This linkage of care to cures is vital to realizing the promise of accelerating clinical and biomedical research to alleviate pain, suffering and death for millions of people.

Again, thank you for the opportunity to present testimony today. And thank you for your continued efforts on behalf of America's patients.

Statement of Mr. Raj Toleti, Galvanon, Maitland, Florida

SUMCOMMITTEE ON HEALTH

Madam Chairwoman and distinguished members of the Subcommittee, thank you for inviting Galvanon to submit a formal statement for the record on the important topic of using patient self-service technology to reduce costs and improve patient care.

I am Raj Toleti, president of Galvanon, a subsidiary of NCR Corporation. Galvanon provides a suite of patient self-service kiosks and Web applications that streamline patient interactions throughout the continuum of care. Our products are designed to help physician groups and hospitals improve workflow, minimize errors and reduce costs.

Background

In today's fast-paced healthcare industry, electronic information management is a crucial tool that has great potential to improve patient care by reducing medical errors, ensuring accurate patient identification, streamlining clinical workflow and facilitating physician access to critical patient health data. Patient self-service applications reduce costly paper-based processes and increase the accuracy of patient data by creating a seamless flow of information from patient check-in through treatment and beyond. Automating the patient registration process eliminates potential errors that stem from redundant data entry while also reducing healthcare costs. Implementing a national healthcare information structure that includes the widespread adoption of patient self-service applications will complement the use of electronic health records and produce enormous benefits in the quality and effectiveness of patient care.

From our experience, we believe the value of collecting data from the patient as early as possible in the treatment process and empowering them to ensure the data is accurate cannot be overstated. Data collection at patient check-in is proven to reduce patient identification errors, medical errors and costs related with duplicative administrative work.

Allowing patients to review, verify and modify their information before it is processed by the healthcare organization benefits patients and providers alike. Providers have access to clean data that enable them to provide the highest possible standard of care and reduces the risks associated with incorrect or inaccurate information. Patients receive the most appropriate medical care and are not burdened with challenges associated with delayed medical payments due to claims processing errors.

Today, more than 50 leading-edge healthcare organizations around the county are using a patient self-service approach for everything from eliminating redundant paperwork to speeding the development of experimental cancer treatments. These comments seek to explain how patient self-service applications can reduce healthcare costs while complementing the adoption of electronic health records nationwide.

Reducing paperwork and administrative costs

As the healthcare industry begins to embrace the broader use of information technology such as electronic medical records and practice management systems, the patient registration process has remained paper-based. As a result, gathering vital information from patients at check-in, including demographic, insurance and medical history information, continues to be a cumbersome and labor-intensive process. Patients must complete stacks of paper forms, which staff members must then re-key into the organization's information system. The result is sluggish productivity, increased wait times and the increased likelihood for error.

By using patient self-service technology to automate this process, healthcare providers can dramatically improve service to patients while also increasing safety, efficiency and accuracy. Patients can check-in for appointments, sign forms electronically and make co-payments, helping to reduce paperwork and the costs associated with printing, managing and storing paper forms. Along the way, all patient information is securely captured and stored to ensure HIPAA compliance.

For example, HOAG Hospital Women's Pavilion in Newport Beach, California, implemented patient self-service technology and their patients now fill out 4–6 fewer paper forms and experience shorter wait times. The same holds true at Newark, New Jersey-based Newark Beth Israel Medical Center where patient check-in time has been reduced by 25% for new patients and by 75% for existing patients. The medical center, which handles 300,000 patient visits a year, has been able to reduce the amount of time its staff members spend managing paper forms by 50%. This extra time frees up staff members to focus on patient-related questions and concerns.

Seamless flow of patient information throughout the healthcare enterprise

To further improve electronic health information management, all of the information captured during the automated patient check-in process, including medical history data, is automatically stored in an organization's clinical data repository or electronic medical records system, eliminating the need for staff to manually re-enter data and reducing the risk of clerical errors. This capability also gives providers quick and easy access to the information they need to effectively treat patients. For example, when patients are routinely asked to update their allergies and medications at each visit, their providers know which treatments or medications to avoid, such as those that may result in dangerous drug interactions.

Without the need to manually enter data from patient forms into the organization's information systems, overall efficiency also increases, giving staff members more time to educate patients about conditions, medications, treatments and surgeries. This helps to make patients more active participants in their own care, a key objective as the industry moves toward the implementation and use of consumer-directed healthcare plans, like health savings accounts, where patients bear a greater responsibility for their health choices.

Many healthcare organizations also use self-service technology to ensure that the proper consent forms have been signed and that patient communications conform to HIPAA guidelines. Once signed, these forms can be passed along to an electronic medical record or other electronic imaging and storage system, helping to reduce liability and the costs associated with managing a paper-based consent process.

The use of patient self-service technology also streamlines the process of collecting secure Medicare documents and Medicare related information from patients at the point of service. Medicare forms such as Medicare Rights, Advance Beneficiary No-

tice and the Medicare Secondary Payer Questionnaire can be presented to patients on a self-service platform with minimal staff intervention. Through the application of adaptive questionnaire technology, patients are presented with these forms and questions dynamically, easing the time it takes staff to collect and explain this information. Staff can set a range of workflow conditions, which may include the patient's insurance type or financial class, along with the hospital or clinic service code for the particular visit.

In addition, Galvanon's self-service technology can integrate directly with a number of automated medical necessity checking applications to further augment a healthcare organization's existing necessity checking workflow. This process greatly improves the patient experience, alleviates much of the staff workflow surrounding Medicare related forms collection and helps reduce claim denials and the rework associated with re-submitting medical claims.

Speeding development of experimental treatments

Earlier this year, Galvanon introduced a new module to our MediKiosk product that streamlines the collection and analysis of patient data for use in clinical trials. By using this module, research facilities can automate clinical surveys and questionnaires through adaptive screening technology that generates additional questions based on previous patient responses. This approach to gathering patient information allows research facilities to tailor the clinical intake process for each patient, increase the quality of data collected, improve subject recruitment for clinical trials and minimize the need for costly, time-consuming paper forms.

Tampa, Fla.-based H. Lee Moffitt Cancer Center and Research Institute, one of the Southeast's leading cancer treatment and research facilities, is currently using this new module to collect medical histories, clinical records, and blood and tissue samples from thousands of patients in an effort to expedite the time it takes to bring experimental therapeutics and other clinical trials to market.

Enhancing screening process

Self-service technology can also be used to facilitate clinical screenings that promote the delivery of preventive care services. At Columbus, Ohio-based Columbus Children's Hospital, 10 pediatric-based primary care clinics have implemented self-service technology to automate a self-report adolescent screening program for at-risk behavior. Upon arrival at the facility, patients use the touch screen interface on the self-service device to complete a health risk assessment questionnaire concerning their use of alcohol and drugs, symptoms and impairments for co-morbid mental disorders and other at-risk behaviors such as suicide ideation and depression.

Within seconds of survey completion, the self-reported results are summarized, scored using pre-defined algorithms, stored in the patient's lab result and made available to physicians during the same-day office visit. Having access to this personalized assessment information allows physicians to provide tailored advice and conduct interventions that are more likely to change patient behavior. In fact, one provider indicated that this screening process resulted in a patient who screened positive for depression breaking down during the appointment. As a result, the provider was able to address the issue immediately and connect the patient with the appropriate services.

The automated screening process has been shown to make adolescents more comfortable revealing information related to at-risk behavior because of the enhanced level of privacy it provides. Columbus Children's Hospital uses this approach to screen more than 200 patients each month and to coordinate further research and follow-up activities, such as continued telephone support services that are consistent with the treatment regimen. As a result, providers have the tools they need to strengthen relationships with patients and establish an ongoing dialogue that promotes compliance with the prescribed plan of care.

Improving access for non-English speaking patients

As the American population continues to become more diverse, language barriers can present a serious challenge for non-English speaking patients seeking care. In fact, according to a recently study published by the Commonwealth Fund, approximately 45 million U.S. residents speak a language other than English at home. Patient self-service technology can help eliminate language barriers by offering check-in services in multiple languages.

Both Harlingen, Texas-based Valley Baptist Healthcare System and Newark Beth Israel Medical Center offer patient check-in in both English and Spanish. By allowing patients to register in the language they prefer, the quality of the data collected increases dramatically.

Minimizing fraud through accurate patient indentification

Santa Barbara, Calif.-based Cottage Health System equipped its patient self-service kiosks with biometric fingerprint imaging capabilities to instantly and accurately identify patients during the check-in process. Upon arrival at the facility, patients have the option of providing a thumbprint or swiping a driver's license, credit card or membership card directly on the kiosk to begin checking-in. In addition to helping ensure accurate patient identification for patient safety purposes and minimizing the potential for duplicate patient records, the technology also helps Cottage to minimize Medicare and Medicaid fraud.

In conclusion, we strongly support the greater use of information technology and are committed to further leveraging the benefits of patient self-service technology to address some of healthcare's biggest challenges, from reducing administrative costs to improving quality of care. By working together with our comprehensive network of healthcare information technology partners, we feel we will be able to establish the most effective, efficient methods for gathering patient information and making it available to providers throughout the continuum of care.

The key to a successful self-service strategy lies in the integration with existing IT infrastructures—such as electronic medical records systems and clinical data repositories—so healthcare organizations can expand this strategy throughout the enterprise to achieve true clinical excellence. Whether identifying patients at check-in or improving provider access to patient information, a successful technology strategy will ultimately impact every step of the care process.

Again, I believe that combining patient self-service applications with electronic health records can dramatically improve the quality and safety of healthcare today while also helping to reduce rising healthcare costs. I urge Congress to consider the benefits of patient self-service applications, described above, and promote the development and adoption of this valuable and cost-effective technology.

Thank you again, Madam Chairwoman for the opportunity to submit a formal statement for the consideration and records of the Subcommittee. I am prepared to answer any questions you may have.

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Statement of Greenway Medical Technologies, Carrollton, Georgia

Thank you very much Chairman Johnson and distinguished members of the Subcommittee and staff. My name is Justin Barnes and I am the Vice President of Marketing and Government Affairs for Greenway Medical Technologies, a leading provider of integrated electronic health record (EHR) and practice management software solutions for physicians' practices. It is always a great honor and pleasure to work with members of Congress and their staff as I believe we all have a common goal to shape the new face of the healthcare industry by utilizing the vast contributions that information technology (IT) offers healthcare providers, payers, physicians and patients in achieving goals of reduced medical errors, lower costs, better quality and improved efficiency within our nation's healthcare system.

In addition to representing Greenway, I am also one of the founders of the HIMSS Electronic Health Record Vendor's Association (EHRVA) and currently reside on the EHRVA Executive Committee and serve as Chair of the Membership Committee. The EHRVA is comprised of the nation's 39 leading EHR companies currently representing roughly 98% of all EHR's implemented today. The goals of Greenway and the EHRVA are the same as those of President Bush in terms of developing an industry-wide strategy for widespread adoption of health information technology (HIT) and for converting these goals into substantial quality and efficiency improvements in less than five to eight years from now.

This Statement focuses on our dedication to assisting Congress and government agencies in achieving our health transformation goal. Greenway and the EHRVA support a truly transparent process and equal collaboration of public and private entities. Over the past year, Greenway and the entire private sector has made significant strides in EHR adoption, interoperability and proven return on investment (ROI) for long-term sustainability of this transformation progress and we will continue to make strides in this reform. We have been successful so far without government intervention or the wasting of any taxpayer dollars. Greenway's customer practices alone have realized an annual $21,600 to $81,500 post-implementation return per physician. With paperwork reduced, collections increased and coding improved, physicians provide a higher quality of care and also operate a more efficient business.

While HIT and EHR adoption currently grows at a record pace, we possess the responsibility to ensure that every policy that is enacted and every rule that is proposed must increase and incentivize HIT adoption. While we applaud the focus that the President, Congress and the U.S. Department of Health & Human Services have applied to this industry transformation, we must ensure that all decisions are created by entities that have the essential experience, dedication and factual evidence necessary to put self-sustaining plans and policy in place.

Greenway guardedly supports the efforts of the Office of the National Coordinator for Health Information Technology (ONCHIT) but believes this Office needs more private sector experience and involvement to create a real 50/50, public/ private collaboration. In ONCHIT's current state, Greenway could not support their codification until their processes become more transparent, physicians point-of-care workflow is respected and EHR certification performs the proper due diligence that is necessary for participation and private sector sustainability. We respectfully advise that all Work Groups, Committees and Boards created under ONCHIT and the American Health Information Community (AHIC) make sure that any mandates or certifications are thoroughly investigated, meticulously created and are proven to increase HIT adoption before becoming imposed on the private sector. It is essential that we continue to increase our HIT adoption rates and keep physician's daily workflow at the forefront of all decision-making in this reform and not succumb to any industry or self-serving lobby.

Greenway is one of several examples of how the private sector is committed to this transformation and has taken charge through leading the health information technology and electronic health record industry. Greenway was founded on the premise that HIT & EHRs dramatically reduce medical errors, lower costs, improve quality and efficiency and create a substantial return on investment for physicians and practices among many other constituencies. Greenway has chosen to focus on the small to mid-size practice community as our customer base consists primarily of practices with between 1–50 physicians. The vast majority of healthcare in this country is delivered in medical offices within the above mentioned market space and this environment will be the essential component in assuring widespread adoption due to the communication these practices have with hospital systems, test laboratories, and other medical practices.

Greenway has also structured its offerings to physician practices into a 10-year business plan mirroring President Bush's own Framework for Strategic Action to ensure that healthcare providers will have quality software solutions that inform clinical practices, interconnect clinicians, personalize patient care and improve the overall population health. By directing our efforts in accordance with those of the president, our customers can rest assured that their investment will consist of a fully-integrated solution streamlining their administrative, clinical and financial processes into an efficient workflow that is consistent with long-term viability.

Besides having the best EHR for their practice, it is also Greenway's belief that physicians need fiscally responsible incentives to increase adoption of HIT at a greater pace. Physicians and their practices are the backbone of the American healthcare system and since they are also small businesses, they are the backbone of our economy as well. Congress and the healthcare industry needs to stay focused on economic sustainability by providing fair, increased reimbursement incentives and by increasing the capital equipment and software purchase deductions allowed under section 179 of the Internal Revenue Code.

However, from our decades of experience, we would not support unfunded government mandates, stark-safe harbor modifications or, as mentioned previously, imposed HIT certifications that are not proven to considerably increase EHR adoption, EHR usability and private sector sustainability. We would suggest any proposed changes in these areas get referred to a congressional or Medicare study to review and understand feasibility, longevity and factual impact on HIT adoption goals. Congress and the U.S. Department of Health & Human Services possess the ability to cripple current and future HIT and EHR adoption if they implement immature or flawed policy.

In all that we are working towards, we must also recognize physicians as consumers and realize and respect the necessity of their services. As absurd as it sounds, can you imagine a community without a physician? Their contribution to each community makes it essential that we offer solutions such as EHRs and proper public policy to help keep them in business. It is our experience that we must keep the physicians daily workflow at the fore-front of all decision-making when discussing how we may impact their offices and practice of medicine. The practical workflow involved in a physician's revenue pipeline is more paramount in EHR selection than any non-essential bells and whistles that might influence a physician's purchasing decision. Greenway and the EHRVA both have presented Use Cases and

"Clinical Test Scenarios" to various Work Groups of the Certification Commission for Health Information Technology (CCHIT) and Health Information Technology Standards Panel (HITSP). These Use Cases and Scenarios were derived from real-life experiences with EHRs implemented today at the point-of-care.

This is an exciting time to help lead the healthcare information technology industry. We have the opportunity to create the most efficient healthcare system for this country and while this is a daunting challenge, it is certainly achievable. However, as we continue to move towards 2014, we want to take the prudent and fiscally responsible steps so that our healthcare vision will transform into a national reality. Speaking on behalf of the private sector, we are ready as an industry to answer the call to work in partnership with Congress and federal agencies in making these goals and the framework our future.

Chairman Johnson and distinguished members of the Subcommittee and staff, I want to thank you for this opportunity and your genuine interest in this vast and important topic. I hope that my comments will help steer ideas and thoughts that can be transmitted into innovative policies shaping the future of healthcare in this country. Thank you very much.

Statement Mary Griskewicz, Healthcare Information and Management Systems Society, Alexandria, Virginia

Madame Chair, Congresswoman Johnson, and distinguished members of the Subcommittee, I am honored to submit this statement for the record. My name is Mary Griskewicz and I have the pleasure of serving as the 2005–2006 Chair of the Healthcare Information and Management Systems Society (HIMSS) Advocacy & Public Policy Steering Committee. I live in Connecticut and work professionally for GE Healthcare, Global Marketing Director of Industry and Government Affairs.

HIMSS is one of the largest healthcare IT trade associations, representing over 17,000 individual members and the 280 corporate members who employ more than 1.2 million people across the United States. On behalf of HIMSS members and the thousands of professionals in the healthcare IT community, we commend you and the members of the Subcommittee on Health for your leadership in promoting initiatives that increase the use of information technology throughout the healthcare industry. HIMSS' vision is to advance the best use of information and management systems for the betterment of healthcare. Our mission is to lead change in the healthcare IT and management systems field through knowledge sharing, advocacy, collaboration, innovation, and community affiliations.

Saving lives and improving patient safety are major goals of the healthcare industry, given the high occurrence of medical errors resulting in up to 100,000 lives lost and up to $29 billion of costs each year in the U.S. alone, according to the Institute of Medicine report, "To Err is Human." Furthermore about 3.7 percent of hospitalizations may be associated with error, and 13.6 percent of these lead to death.

Studies have proven healthcare IT saves money and saves lives. The Center for IT Leadership suggests that utilizing interoperable ambulatory EHRs alone will save $112 billion a year, representing approximately 7 percent of healthcare spending. The ONC conservatively estimates that annual savings due to widespread EHR adoption are likely to range between 7.5 and 30 percent of annual healthcare spending. These are important savings targets as healthcare now consumes 17 percent of our nation's gross domestic product, by far the largest percentage of any nation in the world.

This month, HIMSS' Patient Safety and Quality of Care Steering Committee participated in the National Quality Foundation's (NQF) balloting for National Voluntary Consensus Standards for the Prevention and Care of Venous Thromboembolism (VTE). According to NQF, VTE is the most common preventable cause of death in hospitals. It afflicts 900,000 Americans every year, in 500,000 people this condition advances to pulmonary thromboembolism (hypertension in the lungs) and results in death for approximately 300,000. The U.S. health IT industry is a world leader and this is unacceptable.

IT has transformed every industry in America and the world and we can and will do the same for healthcare. Americans deserve much more than the current mediocre and often failing healthcare delivery system.

There are hospitals, clinics, physician practices, and businesses that are using healthcare IT to save money and save lives every day. In fact, there are numerous success stories across the country that should be replicated. For example, Wayne Obstetrics and Gynecology, with more than 6,000 patient encounters a year, is a

model of excellence for small provider practices in a rural setting. Based in Jessup, Georgia this solo practice views its EHR as a distinct asset in the volatile world of OB malpractice.

We know through EHRs, standards, and legal and financial incentives, we can and must do better. We look forward to continuing to work with you and your colleagues to improve America's health system.

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April 20, 2006

The Honorable Nancy Johnson
Chairman
Subcommittee on Health
House Ways and Means Committee
1136 Longworth House Office Building
Washington, D.C. 20515

Dear Chairman Johnson:

I applaud your efforts to tackle the important issue of health information technology in an effort to reduce medical errors, improve patient care, and reduce costs.

As a follow-up to your April 6, 2006 hearing on "Health Care Information Technology," I wanted to take this opportunity to highlight innovative technology that is in the process of being utilized at hospitals in my district. This technology, designed to help physician groups and hospitals improve workflow, minimize errors, and lower costs, is made by Galvanon, a subsidiary of NCR Corporation that creates solutions to streamline everyday patient interactions and improve patient flow through the health care process.

Columbus Children's Hospital is using what is known as an "eClipboard" to automate the screening process for the Trial of Automated Risk Appraisal for Adolescents (TARAA) Project, a self-report health screening for at-risk behavior. The TARAA project is funded by a grant from the National Institute on Drug Abuse and screens youth for their use of alcohol and drugs, symptoms and impairments for co-morbid mental disorders, and other at-risk behaviors such as suicide ideation and depression.

Upon arrival for an appointment, patients at ten pediatric-based primary care centers use the touch screen interface on the tablet PC device to check in for appointments and complete screening questionnaires. Within seconds of survey completion, the self-reported results are summarized, scored and stored in the patient's chart, and the data is made available to providers during the same-day office visit. Having access to this personalized assessment data enables physicians to provide tailored advice and conduct interventions that are more likely to change patient behavior. In fact, one provider indicated that this screening process resulted in a patient who screened positive for depression breaking down during the appointment. As a result, the provider was able to address the issue immediately and connect the patient with the appropriate services.

The automated screening process has been shown to make adolescents more comfortable revealing information related to alcohol and drug use, depression and other at-risk behavior because of the enhanced level of privacy it provides. It also gives Columbus Children's the data they need to follow-up with patients that screened positive for adverse health conditions so they can deliver care support services consistent with the treatment regimen.

In addition, The Ohio State University Medical Center (OSU) will soon utilize a MediKiosk in the main hospital registration area. Scheduled and walk-in patients will be able to check-in and register for appointments using the kiosk.

The kiosk will become an integral part of OSU's efforts to increase positive identification of patients and increase accuracy of patient records by giving patients control, allowing them to electronically update their demographic, guarantor, emergency contact, and insurance information. In addition, patients will be able to fill out health history information and sign consent forms electronically, helping to create a seamless flow of patient information throughout the organization.

By using these administrative applications, OSU staff will be able to electronically update patient records in their current IDX system. As a result, physicians will have immediate access to the patient's updated health history information, which increases the quality of care the patient receives.

I commend your enthusiasm for tackling this important issue, and I share your belief that we have a significant opportunity to dramatically improve the quality of care for patients across the country while reducing health care costs. Thank you

again for your hard work and for taking into consideration the innovative technology being used at hospitals in my district as you move forward. If I can be of any assistance, please do not hesitate to contact me.

Very truly yours,

Deborah Pryce
Member of Congress

Statement of Congressman Phil Gingrey, a Representative in Congress from the State of Georgia

Chairwoman Johnson, Ranking Member Stark, and Members of the Health Subcommittee, on behalf of the citizens of Georgia's Eleventh Congressional District, thank you for allowing me the opportunity to submit this statement into the record.

Every day we read in the headlines about the rising cost of health care and what it means to every American in this country. More and more businesses are no longer able to afford health care benefits for their employees, too many Americans are uninsured, health care premiums continue to rise each year and the neediest of our nation are not given the access to the quality care they deserve.

There are many ways to tackle the problem of skyrocketing health care costs, but I want to focus on healthcare information technology. Why does Congress need to be invested in the adoption of health care information technology? In September of 2005 RAND released a study that showed how a health information technology system that is implemented correctly and **widely adopted** could save the American health care system more than *$162 billion annually*. Since we all know the tremendous stress our healthcare system is currently operating under, these savings alone are a very compelling justification for congressional involvement. However, it was not until I went out into my district, met with physicians and representatives from the health IT industry that I realized the answer to the question of congressional action.

The key to the report and my personal research centers around the concept of "widely adopted." What role can and should the government play in ensuring healthcare information technology is "widely adopted." There a variety of thoughts, opinions and pieces of legislation centered around this question. The RAND study simply states that in order to take full advantage of this potential savings we need incentives for physicians to buy quality systems. So the question becomes not only what would be the most effective way to incentivize physicians, but what is the most fiscally-responsible way to incentivize physicians.

As a physician Member of Congress, I was anxious to go visit doctors' offices that were utilizing health information technology to see what differences it makes out in the real world. I stopped practicing medicine just three short years ago, and I remember vividly the overwhelming burden of administrative paperwork. It robbed physicians of time with their patients, taking away from them the reason they had decided to go to medical school in the first place. What I saw put into practice was amazing to me.

I visited a three doctor OB/GYN practice in Carrollton, GA, which purchased their electronic health record system in 2002. I was able to watch Dr. Martin as he demonstrated the established routine he follows during a patient visit utilizing his computer tablet. He stated that their vendor company worked hard to ensure the process flowed to his liking and the words and phrases that he used most frequently were utilized in the chart template. It was amazing to me how efficient it was to document a patient's chart, pull up any necessary tests or images; all at the point of care, when it was needed. After my time with Dr. Martin in Carrollton, I realized how revolutionary health IT was to the healthcare world. It transforms how physicians do business on a daily basis by streamlining the process, giving them the tools and the information they need when they need it. It even left me thinking if my political career doesn't work out, how I would want to jump back into medicine with both feet.

My discussions with these physicians, their office managers and representatives from vendor companies, left me astounded by the recurring theme of satisfaction. The physicians I spoke with are enjoying a higher quality of life, more efficiency in follow up with their patients and the flexibility to complete charts and take "call" from the comfort of their home. The office managers spoke emphatically about the almost immediate increased revenue from automating their coding and billing process. Not only did they receive payment from insurance companies quicker; and they received more accurate payments.

An increase in revenue to a physician's bottom line is another of the big wins in purchasing an electronic health record system. The system not only automatically codes the patients' visits but correctly codes the visits to ensure the physician is reimbursed accurately for the services rendered. In medical school, physicians learn quickly that it is easier to "down" code a visit than submit a claim that is rejected by an insurance company which requires your office to resubmit the claim; wasting staff time and taking money away from the practice.

There are perceptions in the health care system and the federal government that there are numerous hurdles preventing physicians from incorporating health IT into their offices. These concerns range from the time and energy required of physicians to learn a new system, a potentially unsustainable decrease in productivity and the natural apprehension that comes with any large financial investment. However, the reality is that an office will see anywhere from $20,000 to $80,000 in ROI per physician each year after implementing an integrated health IT system.

I want to present a specific example of what one practice saw as a return on investment in their first year after purchasing a complete health IT system. I would like to submit for the record an example administered by Microsoft Windows Server System. They performed a customer solution case study on a five doctor, OB/GYN practice in New York that sees about 200 patients a day. For this practice, implementing an integrated electronic health record system has cut down on the administrative work required of each doctor by one hour every day, it has allowed them to see an additional 25 patients each week and has given them a first year return on investment of $407,000.

It is for this particular reason that I believe the best thing Congress can do is to create incentives for physicians to incorporate health information technology into their practices and then get out of the way. This is why I introduced H.R. 4641, the ADOPT Health IT Act, which creates just such incentives by increasing the deductions offered under section 179 of the tax code for health care providers that purchase an EHR system. I have heard from physicians and industry alike that section 179 is the strongest motivation for practices to move into the world of health IT; but it does not extend far enough to be as useful as possible.

Under current tax code, small businesses can deduct around $100,000 of the cost of qualified business expenses that are placed into service that tax year. My legislation increases this maximum deduction to $250,000; therefore, creating a more realistic incentive to spur adoption amongst physician practices of all sizes. The average doctor's office in this country has 4 physicians in its practice. The average cost of a fully integrated and comprehensive health IT system for this type of practice is around $165,000–$175,000.

Currently small businesses have a maximum threshold of $400,000 for qualified equipment purchases in any given year. My legislation would increase that to $600,000, to ensure that practices aren't deciding between upgrading their out of date x-ray machine and investing in health IT.

The logic behind this idea is that physicians, like all small business owners, look at what the tax code can offer them as they consider purchasing equipment for their business.

H.R. 4641 allows Section 179 of the tax code to better represent the actual cost of an EHR system. By appealing to a physician's business instinct and allowing the tax code to provide incentives, we can create a much more effective way of getting health care information technology into every physician's office around the country. These incentives will work far better than simply dumping federal grants into the health care system.

In closing, I again want to express my gratitude for this opportunity and respectfully ask for your consideration of the initiative I laid out today.

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